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The Effect of Arthroscopic Bankart Repair on Shoulder Kinematics and Proprioception in Patients with Traumatic Anterior Shoulder Instability: A Prospective Cohort Study Protocol

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1 The Effect of Arthroscopic Bankart Repair on Shoulder Kinematics and

2 Proprioception in Patients with Traumatic Anterior Shoulder Instability: A

3 Prospective Cohort Study Protocol

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4 17 **Abstract**
5
6 18 Introduction: Traumatic shoulder dislocation is a common shoulder injury, especially among the
7
8 19 young and active population. More than 95% of dislocations are anterior, in which the humeral head
9
10 20 is pushed beyond the anterior glenoid rim. The injury leads to decreased joint stability and
11
12 21 recurrence rates are high. There is evidence that the shoulder biomechanics and neuromuscular
13
14 22 control change following dislocation, but it remains to be established if these parameters are useful
15
16 23 in the clinical setting. The aim of this prospective cohort study is to apply a 360° investigation
17
18 24 approach to patients with traumatic anterior shoulder instability undergoing arthroscopic Bankart
19
20 25 repair. By conducting the study, we wish to establish if biomechanical and neuromuscular
21
22 26 examinations are applicable in the clinical setting to assess shoulder instability and guide surgeons
23
24 27 in timely and evidence-based identification of patients that will benefit from surgery.

28
29 28 Methods and analysis: This is a prospective multicenter cohort study with repeated measures of 55
30
31 29 patients undergoing arthroscopic Bankart repair. With carefully selected and completely non-

32
33 30 invasive examination methods, we will investigate the effect of arthroscopic Bankart procedure

34
35 31 from biomechanical, neuromuscular, clinical, and patient-centered perspectives. The affected

36
37 32 shoulders are tested once pre-surgically and twice post-surgically at 6 and 12 months. Patients'

38
39 33 contralateral shoulders are investigated once to establish a pre-injury (normal) level.

40
41 34 Ethics and dissemination: The study was approved by the Capital Region Ethics Committee

42
43 35 (journal-no: H-21027799) and the Capital Region Knowledge Center for Data Reviews (journal-no:

44
45 36 P-2021-842) before patient recruitment began. The study results will be published in international

46
47 37 peer-reviewed journals, online and in other relevant media, presented at medical conventions and

48
49 38 disseminated to clinicians and patients as appropriate.

50
51 39 Trial registration number: NCT05250388

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4 40 **Keywords:** traumatic shoulder instability, anterior shoulder instability, biomechanics, kinematics,
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6 41 proprioception, neuromuscular control, arthroscopic Bankart repair
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42 **Strengths and limitations**

- 43 • This study has a 360° investigation approach from biomechanical, neuromuscular, clinical, and
44 patient-centered perspectives, which has not been previously described.
- 45 • The study will contribute with increased understanding of traumatic anterior shoulder instability
46 and might lead to an enlargement of the clinical toolbox to help surgeons in choosing between
47 treatment alternatives.
- 48 • All examination methods are non-invasive.
- 49 • The study is essentially exploratory, as the literature on biomechanical and neuromuscular
50 changes in patients with traumatic shoulder instability is scarce and the authors cannot refer to
51 any established standard deviations or minimally important difference.

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4 52 **1. Introduction**
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6 53 **1.1 Background**
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8 54 Traumatic anterior shoulder dislocation is a common shoulder injury, with a prevalence of 1.7% in
9
10 55 a general population aged 18-70 years and incidence rates of 11.2-56.3 per 100'000 person years
11
12 56 [1-3]. First-time dislocation incidence rates are highest in the third decade of life for men, while it
13
14 57 is most common in women above 50 years of age [3] The injury leads to glenohumeral joint
15
16 58 instability and recurrence rates exceed 70% in some reports [4]. Besides disruption and injury to the
17
18 59 capsule, labrum and ligaments, bone loss is often seen after the injury [5]. The bone loss can be
19
20 60 isolated to the anteroinferior part of the glenoid, referred to as the osseous Bankart lesion, or to the
21
22 61 posterolateral aspect of the humeral head, the Hill-Sachs lesion, but can also be seen in combination
23
24 62 as bipolar lesions, creating an additive negative effect on the joint stability [6]. Thus, the extent of
25
26 63 the structural injury plays a role in development of glenohumeral instability.

31
32 64 Chronic shoulder instability may appear even after the first dislocation and often aggravates with
33
34 65 recurrence, which can lead to altered shoulder biomechanics and motion control [5,7-9]. The joint
35
36 66 stability is clinically assessed using manual tests including the sulcus sign, load and shift,
37
38 67 apprehension test, and relocation test; some of which have high specificity, but are highly patient-
39
40 68 and examiner-dependent and none of them provide quantitative data [10]. The instability can be
41
42 69 directly inspected and quantified during arthroscopy, which is an invasive procedure, or through
43
44 70 medical imaging methods, which might be irradiating and, furthermore, only examines the joint in a
45
46 71 static position [6,7,11]. Alternatively, non-invasive and non-irradiating dynamic analysis of the
47
48 72 shoulder biomechanics can be performed using motion capture and ultrasound [9,12-14].

52
53 73 Neuromuscular joint control is most often assessed as joint position sense (JPS) or threshold to
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55 74 detection of motion (TTDM). In 2015, a systematic review concluded that patients suffering from
56
57 75 traumatic anterior shoulder instability had decreased JPS and increased TTDM, thus impaired

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4 76 neuromuscular joint control compared to those with stable/healthy shoulders [15]. Both modalities
5
6 77 have been criticized for the lack of ecological validity, as they are static and without application of
7
8 78 an external force and thereby cannot be generalized to a real-life setting [16]. The shoulder-sway
9 test, developed in 2012, investigates neuromuscular joint control in a loaded static position [17].
10
11 79 Reduced joint control, measured as increased sway-length, has been reported in shoulders with
12
13 80 traumatic anterior instability compared to healthy, which supports the theory of impaired
14
15 81 neuromuscular control in these patients [18]. Recently, the Copenhagen Assessment of
16
17 82 Neuromuscular Control in the Unstable Shoulder (CANCUS) – consisting of the JPS, shoulder-
18
19 83 sway and reaction time tests in a dynamic and loaded setting was developed but remains to be tested
20
21 84 in patients [unpublished test series].
22
23 85 In treatment of traumatic anterior shoulder instability, the focus is on restoring stability. Surgically,
24
25 86 the structural stability is re-established, and the extent of injury determines the type of surgery [6].
26
27 87 Surgery reduces risk of recurrent events but does not always relieve patients of symptoms. Some
28
29 88 patients still experience a feeling of instability – apprehension – after surgery and suffer from
30
31 89 residual pain and reduced activity level and quality of life [9,19,20]. As the pathologic mechanism
32
33 90 of apprehension is complex and probably includes both mechanical and neurological impairments,
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35 91 the effect of surgery might be questioned [21]. More specifically, the effects on biomechanical and
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37 92 neuromuscular properties remain unclear [9,22].
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47 94 **1.2 Research questions**
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49 95 A (biomechanics): Does arthroscopic Bankart repair have a stabilizing effect on the biomechanics
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51 96 in patients with traumatic anterior shoulder instability?
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54 97 B (neuromuscular control): Does arthroscopic Bankart repair improve neuromuscular control in
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56 98 patients with traumatic anterior shoulder instability?

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4 99 C (clinical outcomes): What are the clinical outcomes following arthroscopic Bankart repair?
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8 100 **1.3 Aim**
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10 101 We aim to investigate the effect of arthroscopic Bankart repair on biomechanical, neuromuscular,
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12 102 and clinical outcomes (including patient-reported outcome measures) to test the hypothesis that
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14 103 biomechanical and neuromuscular examinations are clinically applicable in assessment of shoulder
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16 104 instability and can be helpful in guiding surgeons in timely and evidence-based identification of
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18 105 those who will benefit from surgery.
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22 106 **1.4 Objectives**
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25 107 **1.4.1 Objectives research question A**
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27 108 In patients with traumatic anterior shoulder instability undergoing arthroscopic Bankart repair, to
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29 109 investigate the anterior-posterior glenohumeral translation and the scapular rotations before and six
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31 110 and twelve months after surgery and whether the ranges are restored to the same as the healthy
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33 111 contralateral shoulder.
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36 112 **1.4.2 Objectives research question B**
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39 113 In patients with traumatic anterior shoulder instability undergoing arthroscopic Bankart repair, to
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41 114 investigate the neuromuscular control before and six and twelve months after surgery and whether
42
43 115 the neuromuscular control is restored to the same level as the healthy contralateral shoulder.
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46 116 **1.4.3 Objectives research question C**
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48 117 In patients with traumatic anterior shoulder instability undergoing arthroscopic Bankart repair:
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50 118 1) To determine the recurrence rates in the first 12 months.
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52 119 2) To investigate the shoulder range of motion (ROM) before and six and twelve months after
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54 120 surgery.
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57 121 3) To assess the joint instability by manual testing before and six and twelve months after surgery.
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4 122 4) To quantify potential bone loss before surgery.
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6 123 5) To investigate patient-reported outcome measures (PROM) before and six and twelve months
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9 124 after surgery.
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11 125 **1.4.4 Other objectives**
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13 126 To investigate if there are correlations between the shoulder biomechanics and a) neuromuscular
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15 127 control, b) PROM, c) ROM, and d) bone loss.
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19 128 **2. Methods and analysis**
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21 129 **2.1 Study design**
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24 130 This is a prospective observational cohort study with repeated measures of the patient's affected
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26 131 shoulder pre- and post-intervention. The contralateral shoulder is investigated prior to surgery to
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28 132 establish a pre-injury level representing the normal shoulder.
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32 133 **2.2 Outcomes**
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35 134 The outcomes were designed to investigate the effects of arthroscopic Bankart repair using a 360°
36
37 135 approach with biomechanical, neuromuscular, clinical, and patient-centered perspectives (Fig. 1).
38
39
40 136 The change in anterior-posterior glenohumeral translation was chosen as the primary outcome to
41
42 137 allow for a statistic sample size calculation (see section 3.1).
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44
45 138 **2.2.1 Biomechanical outcomes**
46
47 139 The primary outcome is the change in anterior-posterior glenohumeral translation six months after
48
49 140 surgery as assessed from real-time ultrasound imaging. The examination strictly follows a
50
51 141 previously tested protocol in which the joint is tested in two positions: 1) neutral along the body
52
53 142 (posterior view) and 2) in abduction and external rotation (anterior view); under three conditions: 1)
54
55 143 at rest, 2) during isometric force and 3) with external force applied to the relaxed joint [14,23]. The
56
57 144 translation, in millimeters, is calculated by subtracting the distance between the border of the
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4 145 glenoid (posterior view) or the coracoid process (anterior view), respectively, and the border of the
5
6 146 humeral head at rest (condition 1) from the conditions with force applied (conditions 2 and 3). All
7
8 147 ultrasound examinations are carried out by the same investigator. The change in the anterior-
9
10 148 posterior glenohumeral translation is also evaluated 12 months after surgery (same methods as
11
12 149 above).

13
14
15 150 The scapular upward downward rotations, protraction-retraction and anterior-posterior tilt are
16
17 151 analyzed using motion capture technique with a skin-marker based protocol and eight cameras
18
19 152 simultaneously collecting data during ROM activities and used to evaluate the effect of Bankart
20
21 153 repair six and twelve months following surgery. The motion capture protocol was developed in the
22
23 154 Human Movement Analysis Laboratory at Copenhagen University Hospital Hvidovre and has been
24
25 155 previously tested in healthy subjects (article in preparation).

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32 156 **2.2.2 Neuromuscular outcomes**
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34 157 The change in neuromuscular control is assessed using the newly developed CANCUS test protocol
35
36 158 at six and twelve months after surgery. The test series includes assessment of the shoulder joint
37
38 159 reaction time, sway, and joint position sense using motion capture, force platforms and surface
39
40 160 electromyography (EMG). The shoulder reaction time test determines the neuromuscular control in
41
42 161 a loaded and fast dynamic setting. It was developed and tested in healthy subjects in the Human
43
44 162 Movement Analysis Laboratory at Copenhagen University Hospital Hvidovre (article in
45
46 163 preparation). The sway test determines the neuromuscular control in a weightbearing and static
47
48 164 position, using force platforms to determine the center of pressure in the frontal and sagittal planes.
49
50 165 The joint position sense is a slow dynamic, non-weightbearing evaluation of how precisely the
51
52 166 patient can reproduce a given position of the joint. It is tested in an external rotational motion with
53
54 167 the arm in 90° abduction.

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4 168 2.2.3 Clinical and patient-reported outcomes
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6 169 Any recurrent dislocations in the first 12 months are registered during follow-up. Further, the
7
8 170 active shoulder ROM (flexion, extension, abduction, internal and external rotation) is evaluated
9
10 171 using a handheld goniometer before and six and twelve months after surgery. The clinical instability
11
12 172 tests sulcus sign, load and shift, apprehension test and relocation test are performed and evaluated
13
14 173 with dichotomous outcomes at all three visits (positive/negative). The manual tests are performed
15
16 174 by the same investigator.

17
18 175 All patients undergo a pre-surgical computed tomography (CT) scan to measure potential bone loss.
19
20 176 Glenoid bone loss is measured using the PICO-method, which is based on calculating the size of the
21
22 177 defect as the percentage of a best-fit circle from the contralateral glenoid [24]. The size (width and
23
24 178 depth in millimeters) of Hill-Sachs lesions on the humeral head is also measured and registered
25
26 179 [25].

27
28 180 The perceived change in shoulder function is evaluated using the Western Ontario Shoulder
29
30 181 Instability (WOSI) index [26]. It consists of 21 items, each scored on a 100 mm Visual Analogue
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32 182 Scale (VAS). Each item falls into one of the domains of physical function, sports/recreation/work,
33
34 183 lifestyle, and emotional well-being. Each question is scored between 0-100 points and the sum of all
35
36 184 the questions adds up to a final score, ranging from 0 (best) to 2100 (worst).

37
38 185 The perceived change in quality of life is assessed using the EQ-5D questionnaire, which has five
39
40 186 components that assess the severity of problems in three functional dimensions (mobility, self-care
41
42 187 and usual activities) and two somatic symptom dimensions (pain/discomfort and
43
44 188 anxiety/depression) [27]. The response scales consist of a heading and five short statements, each
45
46 189 describing a different level of severity.

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4 190 **2.3 Study setting**

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6 191 The patients are screened for eligibility and treated at five centers specialized in treatment of
7 shoulder instability. The centers include the Department of Orthopedic Surgery, Copenhagen
8 192 University Hospital Amager & Hvidovre, the Department of Orthopedic Surgery, Copenhagen
9 193 University Hospital Herlev & Gentofte, the Department of Orthopedic Surgery, Zealand University
10 194 Hospital Køge, Adeas Hospital, Gildhøj Private Hospital. The final enrolment in the study and all
11 195 study-related investigations are performed at Copenhagen University Hospital Hvidovre. All data
12 196 collection (collection of informed consent, clinical examination, biomechanical and neuromuscular
13 197 examinations, CT scan, and collection of PROMs are performed at Copenhagen University Hospital
14 198 Hvidovre. See Supplement 1 for further general information.

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18 200 **2.4 Study population and eligibility criteria**

19 201 Fifty-five patients with traumatic anterior shoulder instability undergoing arthroscopic Bankart
20 repair will be recruited from the centers listed above.

21 202 Eligibility criteria are age 18-40 years, unilateral traumatic anterior shoulder instability, scheduled
22 for arthroscopic Bankart repair, no pathology in the contralateral shoulder, willingness to adhere to
23 the study protocol, and ability to give informed consent.

24 203 Exclusion criteria are other pathology or associated injuries in the affected shoulder (including
25 traumatic rotator cuff/biceps tendon/SLAP lesion, fracture of proximal humerus/scapula/clavicula,
26 204 dislocation of sternoclavicular or acromioclavicular joint), pregnancy, and severe medical illness
27 205 (American Society of Anesthesiology physical status (ASA) score ≥ 3).
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35 All patients must provide written, informed consent prior to any study procedure (Supplement 2).
36 The consent gives the primary investigator and relevant authorities access to the patient's records,
37 including electronic medical records and audit, hereunder internal audit, and quality assessment,

which are mandatory. The right to access the patient's records is in accordance with the Regional Committee on Health Research Ethics law (§ 3, section 3) and promulgation § 4, section 1, and § 10, sections 3 and 5).

Study inclusion does not influence the treatment course, neither does a decision to withdraw from the study at any point. A patient may be excluded from the study based on the investigator's decision, e.g., in the event of post-surgical complications or inability to adhere to the study protocol. Participants may also be excluded if the study sponsor or government or regulatory authorities terminate the study prior to its planned end date. Patients lost to follow-up are not excluded from analysis but will be specifically accounted for in the report.

2.5 Study plan

There are three visits in total: 1) baseline pre-surgical visit; 2) six months post-surgical ±2 weeks; 3) 12 months post-surgical ±2 weeks. All patients undergo arthroscopic Bankart repair at the center from which they are recruited and follow a standardized post-surgical rehabilitation protocol for a minimum of 12 weeks. All study-related activities are carried out according to the study plan presented in Table 1.

Study plan	Recruitment	Inclusion	Pre-surgical visit	6 months after surgery	12 months after surgery
Setting	Recruiting center	Copenhagen University Hospital Hvidovre			
Eligibility screen	X				
Oral and written study information and enrolment		X			
Written informed consent		X			
Biomechanical outcomes			X	X	X
Neuromuscular outcomes			X	X	X
Clinical outcomes *Computed tomography scan only at pre-surgical visit			X*	X	X
Patient-reported outcome measures			X	X	X

Table 1. Study plan

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4 229 **2.6 Patient involvement**
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7 230 Patients with traumatic anterior shoulder instability have not been involved in formulating the
8
9 231 research questions or choosing the outcome measures. However, they were involved in design of
10
11 232 the examination methods and protocols used in the study. We carefully assess the burden of all
12
13 233 examinations on patients' physical and mental health throughout the study period. The primary
14
15 234 findings will be communicated to the participants.

17
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19 235 **2.7 Statistics**
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22 236 **2.7.1 Sample size calculation**
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24 237 Fifty-five patients will be included in the study, who will each participate with their contralateral
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26 238 shoulder as healthy control. The sample size calculation is based on the primary outcome, set to
27
28 239 detect a mean difference in anterior-posterior glenohumeral translation of ≥ 2.5 mm, with a standard
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30 240 deviation (SD) of 2.3 mm, power of 0.80 (two-sided) and type I error rate of 0.05 for a mixed
31
32 241 effects model [9,28]. With six variables in the analysis (sex, height, BMI, dominant/non-dominant
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34 242 side affected, bone loss, clinical score) and an estimated 15% dropout rate, the calculation resulted
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36 243 in 55 patients.
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41 244 **2.7.2 Statistical analysis**
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43 245 Descriptive statistics will be presented as mean (SD), median (range), and percentages with 95%
44
45 246 confidence intervals as considered appropriate. Normality of data distribution will be tested, and
46
47 247 relevant statistics applied. Results will be evaluated on group level. If data are normally distributed
48
49 248 the primary analysis on baseline data will be a linear regression model stratified for sex and height.
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51 249 Correspondingly, the primary analysis including data after intervention will be a mixed effect model
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53 250 with the variables: sex, height, BMI, dominant/non-dominant side affected, bone loss, and clinical
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4 251 score. If necessary, other relevant statistic models will be chosen according to the characteristics
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6 252 and distribution of the variables.
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10 253 **3. Ethics and dissemination**

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12 254 **3.1 Quality**

13
14 255 The validity and inter-rater reliability of the motion capture model for analysis of scapular rotations
15
16 256 were established by the research group prior to study start. The reliability of the ultrasound
17
18 257 technique has a reported test-retest measurement error of 0.2-0.6 mm [29]. For the CANCUS test
19
20 258 series, the construct validity and intra-rater reliability of each test is established concurrently during
21
22 259 the study. The demographics and clinical examination sheet, as well as PROM questionnaires can
23
24 259 be found in Supplement 3 (clinical examination sheet and PROM questionnaires in Danish).
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29 261 **3.2 Risks, side effects and adverse events**

30
31 262 The clinical examination and manual tests are clinical practice and not considered to be a risk for
32
33 263 the participants. The motion capture model and ultrasound technique are non-invasive and not
34
35 264 considered to induce any discomfort during the tests. When removing the skin-mounted markers
36
37 265 following motion capture and EMG investigations the patient might experience slight discomfort
38
39 266 from the pull on the skin and possible loss of hair, like removal of a band-aid. Some people might
40
41 266 have a temporary redness on the skin, which might be eased with normal body lotion. The arm
42
43 267 movements included in the experiment does not exceed normal functional use of the upper limb but
44
45 268 might induce apprehension of short duration. As for the assessment of neuromuscular control a
46
47 269 transient discomfort during the tests is expected with increasing stress on the glenohumeral joint.
48
49 270 Before each test, the ROM of the patient is tested and is not exceeded. If the patient cannot achieve
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51 271 the ROM required for the test to be carried out, the patient is excluded from the specific test.
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4 273 The radiation acquired during a diagnostic shoulder CT scan with the scanners that are currently
5 operating at the Department of Radiology at Copenhagen University Hospital Hvidovre, with an
6
7 274 average dose-length product (DLP) of 225 mGy*cm, the effective dose of 2.9 mSv (data acquired
8 from 41 shoulder scans performed January–November 2020) is comparable with approximately one
9
10 275 year of background radiation in Denmark (3 mSv). The increased all-time risk of developing cancer
11
12 276 is estimated to 0.038% and 0.0618% for 20-year old male and female subjects at one examination,
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14 277 with radiation levels obtained by the planned examination [30]. The variation in risk between the
15
16 278 sexes is mainly caused by radiation sensitivity of breast tissue in females.
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24 281 No severe safety issues are expected. However, there is always a risk of unknown side effects. In
25
26 282 this context, adverse events are defined as any unintended, unfavorable finding, symptom or disease
27 that occurs, whether it is related to the study or not. Adverse events are recorded. A critical adverse
28
29 283 event is defined as an event or reaction, which causes death, life-threatening situations,
30
31 284 hospitalization, or permanent or severe disability. Critical adverse events must be assessed by an
32
33 285 investigator to consider whether there is a reasonable possibility that it is caused by any procedure
34
35 286 related to the study. The following factors are included in the assessment: consistency in time,
36
37 287 consistency with the known effects of participation, and alternative causes. If a critical adverse
38
39 288 event is considered to have a causal relationship with the participation, the primary investigator, the
40
41 289 clinically responsible and the other investigators will evaluate whether the study should be
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43 290 terminated.
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50 292 **3.3 Education and training**

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52 293 The data collection is conducted by the primary investigator, or experienced staff appointed by the
53
54 294 primary investigator. Before commencing data collection, all involved staff is educated and trained
55
56 in the examination methods and questionnaires to be as calibrated as possible against each other.
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4 296 There is a Standard Operating Procedures (SOP) file at all recruiting centers. In case a patient, from
5 questionnaires or when examined, shows signs or symptoms of affected mental or physical health
6
7 297 the primary investigator is to be informed immediately, and appropriate measures carefully
8 considered (termination of participation, treatment continuation, referral to general
9
10 298 practitioner/therapist/psychologist/psychiatrist).
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17 301 **3.4 Ethical considerations**

18
19 302 All recruiting centers are specialized in treatment of patients with a wide variety of shoulder
20 pathologies, including traumatic instability. The study methods have been chosen specifically to
21 303 answer the research questions and for the objectives stated above. From the study results, we expect
22
23 304 to contribute to the understanding of the pathophysiology of traumatic anterior shoulder instability
24
25 305 and increase awareness of biomechanical and neuromuscular properties. We believe that the
26
27 306 potential benefits of using the chosen methods and enabling more efficient diagnostics, monitoring,
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29 307 and treatment exceed the potential inconveniences of the study participants. The study is carried out
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31 308 in accordance with the principles of the Helsinki Declaration and guidelines for Good Clinical
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33 309 Practice (GCP).
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41 311 **3.5 Approvals**

42
43 312 The study was approved by the Capital Region Ethics Committee (journal-no: H-21027799) and the
44
45 313 Capital Region Knowledge Center for Data Reviews (journal-no: P-2021-842) before patient
46 recruitment began. The primary investigator is responsible of informing the Regional Committee on
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48 314 Health Research Ethics of any critical adverse event and/or major changes of the protocol and files
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50 315 all correspondences.
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4 317 **3.6 Data Management and Confidentiality**

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6 318 The study follows rules on data protection according to the Danish Data Protection Act throughout
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8 319 the complete study period. The primary investigator, supervisors, and other assigned research staff
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10 320 have access to the dataset. The patients are identified by an assigned number. At the completion of
11
12 321 the study all identifiable data will be destroyed. The patients receive verbal and written information
13
14 322 that data is stored and analyzed digitally, that the patient's anonymity is preserved, and that the data
15
16 323 protection legislation is adhered to.
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20 324 The PROM questionnaires are managed using the software Research Electronic Data Capture
21
22 325 (REDCap), a web application for database management originally created at Vanderbilt University.
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26 326 **3.7 Dissemination**
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28 327 The results will be presented in three articles with the preliminary titles:
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- 30 328 1. *The effect of arthroscopic Bankart repair on shoulder biomechanics in patients with traumatic
31 329 anterior instability: A prospective cohort study*
32
33 329 2. *The effect of arthroscopic Bankart repair on neuromuscular control in patients with traumatic
34 330 anterior shoulder instability: A prospective cohort study*
35
36 330 3. *Clinical outcomes following arthroscopic Bankart repair in patients with traumatic anterior
37 331 shoulder instability: A prospective cohort study*
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40 332
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43
44 45 334 The study results will be published in international peer-reviewed journals, online and in other
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46 335 relevant media, presented at medical conventions and disseminated to clinicians and patients as
47
48 336 appropriate. Authorship is given based on the Vancouver criteria.
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53 337 **4. Trial status**
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55 338 Patient recruitment began 1 April 2022 and is expected to last for 24 months.
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58 339 **5. Discussion**
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4 340 The shoulder joint is the most mobile of all human joints and consequently the most unstable. The
5 shoulder is in fact the most commonly dislocated joint in the body. The resulting shoulder
6 instability leads to pain, weakness, and loss of shoulder function, and can have life-lasting
7 consequences. Understanding of the complete damage caused by shoulder dislocation is lacking and
8 management of the condition is incomplete. There is evidence that biomechanics and
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6. Data availability statement

No data are currently available for sharing.

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4 359 7. References
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4 452 **Footnotes:**
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6
7 453 Contributors: CM and KWB initiated the study. CM, KRA, BHK and JB planned the study and
8
9 454 developed the protocol. KWB and PH provided critical feedback about the protocol. Data
10
11 455 acquisition is performed by CM and KRA, who will also analyze the data. All authors have read
12
13 456 and contributed to the manuscript above, given approval, and agreed to be accountable for all
14
15 457 aspects of the work.

17
18 458 Funding: The study is a part of the PhD-project titled “Anterior-posterior glenohumeral translation
19
20 459 in traumatic anterior shoulder instability” funded partially by the Department of Orthopedic
21
22 460 Surgery, Copenhagen University Hospital Hvidovre (PhD-school, salary, overhead, lab costs). The
23
24 461 PhD project has received a grant from the private fund “Familien Hede Nielsens Fond” to cover
25
26 462 examination costs, whom did not have any involvement in study design; in the collection, analysis,
27
28 463 and interpretation of data; in the writing of the report; nor in the decision to submit the article for
29
30 464 publication. Further, the primary investigator has received a grant from the Copenhagen University
31
32 465 Hospital Amager & Hvidovre research fund to cover salary.

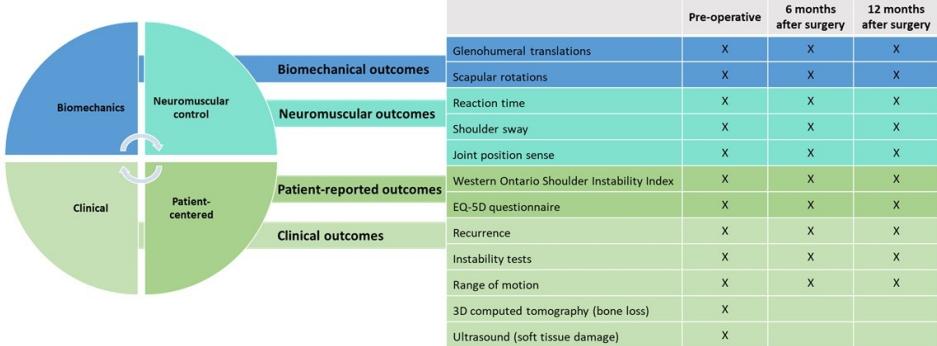
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34 466 Competing interests: None declared.

35
36 467 Patient involvement: Patients were not involved in formulating the research questions or choosing
37
38 468 the outcome measures. Patients were involved in design of the examination methods and protocols
39
40 469 used in the study. The primary findings will be communicated to the participants. Further details
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42 470 can be found in section 2.6.

43
44 471 Provenance and peer review: Not commissioned; externally peer reviewed.

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4 472 **Figure legends:**
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7 473 **Figure 1.** The 360° investigation approach with biomechanical, neuromuscular, patient-centered,
8 and clinical outcomes.
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For peer review only



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The Effect of Arthroscopic Bankart Repair on Shoulder Kinematics and Proprioception in Patients with Traumatic Anterior Shoulder Instability: A Prospective Cohort Study Protocol

1 General information

2 1. Place of investigation

3 Sports Orthopedic Research Center – Copenhagen (SORC-C) and Human Movement Analysis
4 Laboratory, Department of Orthopedic Surgery, Copenhagen University Hospital Hvidovre,
5 Kettegård Allé 30, 2650 Hvidovre, Denmark

6 2. Trial period

7 Anticipated: 1 April 2022 – 1 April 2025.

8 3. Trial registration

9 The study protocol (Version 1.0) was published at Clinical Trials 27 April 2022
10 (www.clinicaltrials.gov, ID: NCT05250388) according to the World Health Organization Trial
11 Registration Data Set and follows the Standard Protocol Items: Recommendations for Interventional
12 Trials (SPIRIT) checklist. The study will adhere to the STROBE guidelines for reporting of cohort
13 studies (www.strobe-statement.org). The study has been approved by the Capital Region Ethics
14 Committee (journal-no: H-21027799) and the Capital Region Knowledge Center for Data Reviews
15 (journal-no: P-2021-842).

16 4. Funding and insurance

17 The study is a part of the PhD-project titled “Anterior-posterior glenohumeral translation in
18 traumatic anterior shoulder instability” funded partially by the Department of Orthopedic Surgery,
19 Copenhagen University Hospital Hvidovre (PhD-school, salary, overhead, lab costs). The PhD
20 project has received a grant from the private fund “Familien Hede Nielsens Fond” to cover
21 examination costs, whom did not have any involvement in study design; in the collection, analysis,
22 and interpretation of data; in the writing of the report; nor in the decision to submit the article for
23 publication. Further, the primary investigator has received a grant from the Copenhagen University

1 The Effect of Arthroscopic Bankart Repair on Shoulder Kinematics and Proprioception in Patients with Traumatic
2 Anterior Shoulder Instability: A Prospective Cohort Study Protocol
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4 24 Hospital Amager & Hvidovre research fund to cover salary. Further fundraising will continuously
5 25 be carried out through public and private foundations. There are no financial disclosures, from
6
7 26 private companies, research funds etc., within the research group that can compromise the integrity
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9 27 of the project.
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14 28 Study participants will not receive financial compensation. Study participants are covered by the
15
16 29 patient insurance of Copenhagen University Hospital Hvidovre.
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20 30 **5. Research group**
21

22 31 *Primary investigator*

23 32 Catarina Malmberg (CM) is MD and PhD-student at the Department of Orthopedic Surgery,
24
25 33 Copenhagen University Hospital Hvidovre, and is the primary investigator, responsible for planning
26
27 34 and conducting the study in all its phases, as well as reporting to all relevant agencies. CM will be
28
29 35 first author of the paper on glenohumeral translation.
30
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35 36 Address: Sports Orthopedic Research Center – Copenhagen (SORC-C), Department of Orthopedic
36
37 37 Surgery, Copenhagen University Hospital Hvidovre, Kettegård Allé 30, 2650 Hvidovre, Denmark
38
39 40 Telephone: +4527519524, Email: catarina.anna.evelina.malmberg.02@regionh.dk
40
41

42 43 *Principal supervisor*

44 45 Kristoffer Weisskirchner Barfod is MD, PhD, and clinical associate professor at the Department of
46
47 46 Orthopedic Surgery, Copenhagen University Hospital Hvidovre. The principal supervisor of the
48
49 47 PhD follows requirements from the University of Copenhagen PhD-school throughout the PhD-
50
51 48 program. Barfod initiated the study together with CM and contributes to planning of the study and
52
53 49 review of the papers.
54
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1 The Effect of Arthroscopic Bankart Repair on Shoulder Kinematics and Proprioception in Patients with Traumatic
2 Anterior Shoulder Instability: A Prospective Cohort Study Protocol
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4 45 *Co-supervisors*
5

6 46 Jesper Bencke is MSc, PhD, and biomechanical laboratory manager at the Department of
7
8 47 Orthopedic Surgery, Copenhagen University Hospital Hvidovre. Bencke contributes to planning of
9
10 48 the study and review of the papers. Bencke also consults the project with his knowledge in the
11
12 49 biomechanical and physiological field and supervise in the biomechanical laboratory.
13
14

15 50 Per Hölmich is DMSc, professor, and chief surgeon at the Arthroscopic Section, Department of
16
17 51 Orthopedic Surgery, Copenhagen University Hospital Hvidovre. Hölmich holds the responsibility
18
19 52 to secure that patients participating in the study are treated according to the highest medical
20
21 53 standard. Hölmich contributes to planning of the study and review of the papers.
22
23

24 54 *Collaborators*
25
26

27 55 Kristine Rask Andreasen, MD and PhD-student at the Department of Orthopedic Surgery,
28
29 56 Copenhagen University Hospital Hvidovre. Andreasen will assist in planning and managing the
30
31 57 neuromuscular tests, hereunder experimental work, clinical examinations, and data collection.
32
33 58 Andreasen will be first author of the paper on neuromuscular control.
34
35

36 59 Birgitte Hougs Kjær is MSc, PhD and Postdoc at the Department of Physical and Occupational
37
38 60 Therapy, Institute of Sports Medicine Copenhagen (ISMC), Copenhagen University Hospital
41
42 61 Bispebjerg & Frederiksberg. Hougs Kjær has specialized experience in musculoskeletal ultrasound
43
44 62 imaging and trained the primary investigator in performing the relevant examinations. Hougs Kjær
45
46 63 also contributes to planning of the study and review of the paper on glenohumeral translation.
47
48

49 64 Sanja Bay Hansen is MD at the Centre for Functional and Diagnostic Imaging and Research,
50
51 65 Dept. of Radiology, Hvidovre hospital. Hansen is responsible for quantifying bone loss from the
52
53 66 computed tomography (CT) scans according to state-of-the-art.
54

1 The Effect of Arthroscopic Bankart Repair on Shoulder Kinematics and Proprioception in Patients with Traumatic
2 Anterior Shoulder Instability: A Prospective Cohort Study Protocol
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4 67 Klaus Bak is MD and senior consultant at the Adeas hospital, Denmark. Bak is associate editor for
5
6 68 the medical journal Knee Surgery, Sports Traumatology, Arthroscopy (KSSTA). Bak contributes as
7
8 69 external assessor of the project.
9

10 12 *Recruiting centers*
11 13

14 71 Department of Orthopedic Surgery, Copenhagen University Hospital Amager & Hvidovre
15

16 72 Department of Orthopedic Surgery, Copenhagen University Hospital Herlev & Gentofte
17

18 73 Department of Orthopedic Surgery, Zealand University Hospital Køge
19

20 74 Adeas Hospitals
21

22 75 Gildhøj Private Hospital
23



Information om forskningsprojektet 'Effekten af kikkertoperation på skulderstabiliteten hos patienter med instabilitet efter traume'

Du er blevet tilset af en ortopædkirurgisk læge, som har konstateret forreste skulderinstabilitet som skal behandles med kikkertoperation.



Vi ved at operation virker godt for langt de fleste, og vi vil med dette forskningsprojekt undersøge hvorfor resultaterne er gode hos mange, men mindre gode hos andre. Vi vil undersøge hvordan operationen påvirker dine ledbånd, dine refleksbuer og din muskulære styring af skulderen. Herved håber vi på sigt at kunne forbedre behandlingen af de patienter som ikke opnår optimale resultater efter operation.

Den projektansvarlige vil efter dette besøg kigge på dine data og kontakte dig via telefon, for at høre om du er interesseret i at høre nærmere om projektet. Hvis det er tilfældet vil vi invitere dig til en samtale, hvor vi gennemgår den skriftlige deltagerinformation og du kan tage endelig stilling til, om du vil være med i projektet.

Forskningsprojektet ændrer ikke på din behandling, men du vil blive indkaldt til 3 ekstra undersøgelser (før operationen, samt hhv. 6 og 12 måneder efter operationen) og du vil få foretaget en udvidet røntgenundersøgelse (3D CT-scanning) af dine skuldre før operationen.

Du kan læse nærmere om forskningsprojektet i den vedlagte deltagerinformation.

Hvis du spørgsmål er du velkommen til at kontakte mig via nedenstående mail eller telefonnummer.

Mvh

Catarina Malmberg, læge, PhD-studerende og projektansvarlige

Mail: catarina.anna.evelina.malmberg.02@regionh.dk

Telefonnummer: 2751 9524



En undersøgelse af effekten af kikkertkirurgi på skulderstabiliteten hos patienter med instabilitet efter traume

Vil du deltag i et videnskabeligt forsøg?

Vi vil spørge, om du vil deltag i et sundhedsvidenskabeligt forskningsprojekt, der udføres af Ortopædkirurgisk afdeling på Hvidovre Hospital. Overordnet ansvarlig for forsøget er læge og PhD-studerende Catarina Malmberg.

Før du beslutter, om du vil deltage i forsøget, skal du fuldt ud forstå, hvad forsøget går ud på, og hvorfor vi gennemfører forsøget. Vi vil derfor bede dig om at læse denne deltagerinformation grundigt.

Udover denne pjece, vil du have en samtale med en af projektets forskere om forsøget, hvor deltagerinformationen vil blive uddybet, og hvor du kan stille de spørgsmål, du har om forsøget. Du er velkommen til at have et familiemedlem, en ven eller en bekendt med til samtalen.

Hvis du beslutter dig for at deltage i forsøget, vil vi bede dig om at underskrive en samtykkeerklæring. Husk, at du har ret til betænkningstid, før du beslutter, om du vil underskrive samtykkeerklæringen.

Det er frivilligt at deltage i forsøget. Du kan når som helst og uden at give en grund trække dit samtykke tilbage uden videre konsekvenser.

Formålet med forsøget

Skulderen er det led i kroppen som hyppigst går af led. Skaden medfører en instabilitet i leddet, og hos mange medfører det nedsat funktion, kroniske smerter og forringet livskvalitet. Om de fortsatte problemer skyldes at ledbåndene rives over, at knoglen deformeres, at nervernes refleksbuer ændres, eller en kombination af ovenstående som medfører at af evnen til styre skulderen går tabt, vides endnu ikke.

Typisk vil første behandlingsvalg være fysioterapi og ved manglende effekt kikkertoperation med genskabelse af leddets stabiliserende strukturer. Med dette studie ønsker vi at undersøge operationens effekt, dels på den mekaniske stabilitet og dels på nervernes refleksbuer (den neuromuskulære kontrol), og afklare om disse faktorer kan forklare de symptomer patienter oplever. Vores håb er på sigt at kunne adskille dem, som kan forvente et godt resultat ved fysioterapi fra dem, som vil have gavn af tidlig kirurgisk behandling. Det ville medføre at man tidligt i forløbet vil kunne finde den behandling som fører til bedst mulige slutresultat, og derved bidrage til en mere effektiv og korrekt behandling af skulderinstabilitet.

Studiet udføres på Hvidovre Hospital, hvor alle kontroller vil finde sted. 55 patienter med traumatisk skulderinstabilitet og planlagt kikkertoperation vil blive inviteret til at deltage, med start fra 1. september 2021.

Forsøgets praktiske udførelse

Som deltager i projektet vil du skulle møde til 3 kontroller; før din operation, samt hhv. 6 og 12 måneder efter operationen. Det forventes at hvert besøg vil vare ca. 2 timer. Ved disse besøg skal du møde i Bevægelseslaboratoriet i Ortopædkirurgisk afdeling på Hvidovre hospital, hvor en fagkyndig person vil undersøge dine skuldre med en række forskellige stabilitets- og funktionstests.



Først vil vi lave en almindelig skulderundersøgelse, ligesom den Du tidligere har fået foretaget hos den kirurg som skal operere dig. Det indebærer, at vi vil bede dig om at bevæge armene i det omfang du kan, samt med vores hænder mærke efter om vi kan fremkalde den løshed og gener som du oplever.

Desuden vil vi ved de tre besøg udføre tests i laboratoriet, hvor vi med højteknologiske hjælpemidler analyserer dine skuldres bevægelsesmønster og din evne til at lokalisere arm og skulder i rummet. Disse inkluderer:

- En test hvor du får påklistret en række markører på og omkring din skulder og bliver bedt om at udføre nogle bestemte bevægelser, samtidig med du bliver filmet. Et antal kameraer i laboratoriet opsamler signaler fra markørerne, som føres videre til en computer, og som beregner og analyserer dit bevægelsesmønster.
- En undersøgelse hvor vi placerer din arm i to forskellige positioner, og med ultralyd kigger direkte ind i dit skulderled samtidig med at du er: i hvile, får et let tryk bagfra, eller drejer din arm enten indad eller udad.
- En test af stillingssans hvor du med lukkede øjne bliver bedt om at genfinde en tidligere position, hvor armen var løftet.
- En "svajetest" hvor du ligger i en plankeposition med underkroppen støttet af en briks og, hhv. med ansigtet nedad og til siden, støtter på skiftevis den ene og den anden arm i 30 sekunder.
- En test af reaktionstid, hvor du bærer et armbånd, der via en ledning over en trisse er forbundet til en elektromagnet med en lodret hængende vægt som trækker let i din arm. Pludselig deaktiveres magneten, og håndvægten slipper, hvilket vil få din skulder at bevæge sig i modsat retning. Den tid du bruger på at reagere, og føre hånden tilbage til udgangspositionen, er reaktionstiden.

Du vil desuden få tilsendt 2 elektroniske spørgeskemaer på mail, vedrørende din skulderfunktion- og smerter, som du vil blive bedt om at udfylde i forbindelse med de tre kontroller.

Inden operationen vil vi foretage en udvidet computerassisteret tomografi (3D CT-scanning) af begge dine skuldre for at vurdere størrelsen af et eventuel knogletab.

Vi vil sammen fastlægge en dato for næste kontrol fra gang til gang, under hensyn til, hvad der er hensigtsmæssigt for dig.

Medicin

Som deltager i projektet vil du ikke skulle tage nogen medicin, og det har ingen indflydelse på medicin som du eventuelt tager i forvejen.

Personlige og journaloplysninger

Ved at skrive under på det informerede samtykke gives forsøgsansvarlige, samt eventuel kontrolmyndighed direkte adgang til at indhente oplysninger i din journal mv., herunder elektronisk journal, med henblik på at se oplysninger om dine helbredsforhold, som er nødvendige som led i gennemførelsen af forskningsprojektet samt i kontroløjemed, herunder egenkontrol, kvalitetskontrol og monitorering, som disse er forpligtet til at udføre. Der henvises til komitelovens § 3, stk. 3 og anmeldelsesbekendtgørelsen § 4, stk. 1, samt § 10, stk. 3 og stk. 5.

De journaloplysninger der er relevante for os er:

1. Dine kontaktoplysninger, som vi anvender til at kontakte dig ud fra.
2. Informationer omhandlende behandling af din skulder, for at sikre at du opfylder kriterierne for deltagelse.
3. Dine billeddiagnostiske undersøgelser (røntgen, CT-scanning), som vi bruger til at undersøge et eventuelt knogletab.



Alle involverede forskere har tavshedspligt og vil behandle dine personlige data strengt fortroligt. Personlige oplysninger vil i gennem hele forsøgets forløb beskyttes ifølge den Danske Databeskyttelsesforordning og Databeskyttelsesloven. Det skal understreges at resultater udelukkende vil blive offentliggjort i anonymiseret form, og hverken navn, CPR- eller deltagernummer vil figurere andre steder end på et sikret, lukket drev. Hvis du vælger at trække dit informerede samtykke tilbage vil ingen nye data blive indsamlet og registreret. Imidlertid tillader lovgivningen, at data indsamlet inden du trækker dit samtykke tilbage stadig indgår i forsøgets datamateriale.

Forsøgets nytte

Som deltager i projektet vil du få en grundig opfølgning af fagpersoner specialiseret i din type skade. Derudover vil du med din deltagelse medvirke til at forbedre undersøgelse og behandling af skulderinstabilitet.

Bivirkninger, risici, og ulemper

Det er en ulempe for dig at skulle møde til de 3 kontroller. Til gengæld får du en grundig opfølgning af din skulder, som potentielt kan bidrage til, at du hurtigere genvinder din oprindelige funktion. Derudover vil din deltagelse i projektet ikke have indflydelse på din behandling.

Den røntgenundersøgelse som vil blive foretaget inden operationen medfører stråling, som potentielt kan øge livstidsrisikoen for kræft. Denne risiko er dog meget lille, og mængden af stråling kan sammenlignes med et års baggrundsstråling i Danmark.

De undersøgelsesmetoder som er inkluderede i projektet i øvrigt er ikke forbundet med kendte sundhedsskadelige risici, men der kan være risici ved forsøget, som vi endnu ikke kender. Under nogle af undersøgelerne vil din skulder være i positioner som kan fremkalde symptomer som smerter, usikkerhed og ubehag. De vil formentlig ligne de symptomer som du i forvejen oplever fra din skulder. Der vil i hele forløbet være en fagkyndig person til stede, med overblik over om undersøgelsen skal pauseres eller afbrydes. Vi beder dig derfor om at fortælle, hvis du oplever problemer med dit helbred, mens forsøget står på. Hvis vi opdager bivirkninger, som vi ikke allerede har fortalt dig om, vil du naturligvis blive orienteret med det samme, og du vil skulle tage stilling til, om du ønsker at fortsætte forsøget.

Udelukkelse fra/afbrydelse af forsøg

Vurderes det, at du ikke følger forsøgsplanen eller oplever bivirkninger som kan påvirke dit fysiske eller psykiske helbred kan du udelukkes fra videre deltagelse i forsøget. Opstår der alvorlige uventede bivirkninger vil forsøget blive afbrudt. Andre årsager til afbrydelse af studiet kan være mangel på deltagere, eller at sufficient datamængde foreligger.

Økonomiske forhold

Der udbetales IKKE vederlag for deltagelse i forsøget. I tilfælde af komplikationer, er deltageren dækket af Hvidovre Hospitals patientforsikring og arbejdsskadeforsikringsloven.

Læge og PhD-studerende Catarina Malmberg og overlæge og klinisk lektor Kristoffer W Barfod har taget initiativ til projektet. Faciliteter i form af undersøgelseslokaler og røntgen stilles til rådighed af Hvidovre Hospital, og projektet finansieres overordnet af Ortopædkirurgisk afdeling. Forsøget har modtaget 20 000 kr. i støtte fra Familien Hede Nielsens Fond. Der søges om yderligere finansiering fra private og offentlige fonde. Hvis yderligere støtte modtages, vil deltagere og Videnskabsetisk Komité blive kontaktet herom. De



involverede forskere har ingen økonomisk udbytte af studiet.

Adgang til forsøgsresultater

Resultaterne vil blive offentliggjort, og udgivet i et internationalt videnskabeligt tidsskrift. Yderligere vil resultaterne blive fremlagt på fagspecifikke kongresser.

Forsøget anses for afsluttet når 55 deltagere har gennemført forsøget. Dette forventes udført inden udgangen af september 2024.

Originaltitel

Forsøgets engelske originaltitel er: 'The effect of arthroscopic Bankart repair on anterior-posterior glenohumeral translation and shoulder proprioception in patients with traumatic anterior shoulder instability: a prospective cohort study'

Det er frivilligt at deltage i forsøget

Vi håber, at du med denne information har fået tilstrækkeligt indblik i, hvad det vil sige at deltage i forsøget, og at du føler dig rustet til at tage beslutningen om din eventuelle deltagelse. Vi beder dig også om at læse det vedlagte materiale "Forsøgspersonens rettigheder i et sundhedsvidenskabeligt forskningsprojekt".

Yderligere oplysninger om forsøget kan fås ved kontakt til projektansvarlig:

Læge, PhD-studerende Catarina Malmberg
Ortopædkirurgisk ambulatorium, afsnit 333, Hvidovre Hospital
Kettegård Allé 30, 2650 Hvidovre
Mail: catarina.anna.evelina.malmberg.02@regionh.dk
Telefon: 27519524 / 38623862

Forsøgspersoners rettigheder i et sundhedsvidenskabeligt forskningsprojekt

Som deltager i et sundhedsvidenskabeligt forskningsprojekt skal du vide, at:

- din deltagelse i forskningsprojektet er helt frivillig og kun kan ske efter, at du har fået både skriftlig og mundtlig information om forskningsprojektet og underskrevet samtykkeerklæringen.
- du til enhver tid mundtligt, skriftligt eller ved anden klar tilkendegivelse kan trække dit samtykke til deltagelse tilbage og udtræde af forskningsprojektet. Såfremt du trækker dit samtykke tilbage påvirker dette ikke din ret til nuværende eller fremtidig behandling eller andre rettigheder, som du måtte have.
- du har ret til at tage et familiemedlem, en ven eller en bekendt med til informationssamtalen.
- du har ret til betænkningstid, før du underskriver samtykkeerklæringen.
- oplysninger om dine helbredsforhold, øvrige rent private forhold og andre fortrolige oplysninger om dig, som fremkommer i forbindelse med forskningsprojektet, er omfattet af tavshedspligt.
- behandling af oplysninger om dig, herunder oplysninger i dine blodprøver og væv, sker efter reglerne i databeskyttelsesforordningen, databeskyttelsesloven samt sundhedsloven. Den dataansvarlige i forsøget skal orientere dig nærmere om dine rettigheder efter databeskyttelsesreglerne.
- der er mulighed for at få aktindsigt i forsøgsprotokoller efter offentlighedslovens bestemmelser. Det vil sige, at du kan få adgang til at se alle papirer vedrørende forsøgets tilrettelæggelse, bortset fra de dele, som indeholder forretningshemmeligheder eller fortrolige oplysninger om andre.
- der er mulighed for at klage og få erstatning efter reglerne i lov om klage- og erstatningsadgang inden for sundhedsvæsenet. Hvis der under forsøget skulle opstå en skade kan du henvende dig til Patienterstatningen, se nærmere på www.patienterstatningen.dk

De Videnskabsetiske Komiteer for Region Hovedstaden (6 komiteer)
Tlf.: +45 38 66 63 95
E-mail: vek@regionh.dk
Hjemmeside: www.regionh.dk/vek

Den Videnskabsetiske Komité for Region Sjælland
Tlf.: +45 93 56 60 00
E-mail: RVK-sjaelland@regionsjaelland.dk
Hjemmeside: <https://www.regionsjaelland.dk/sundhed/forskning/forfagfolk/videnskabsetisk-komite/Sider/default.aspx>

De Videnskabsetiske Komiteer for Region Syddanmark (2 komiteer)
Tlf.: +45 76 63 82 21
E-mail: komite@rsyd.dk
Hjemmeside: www.regionssyddanmark.dk/komite

De Videnskabsetiske Komiteer for Region Midtjylland (2 komiteer)
Tlf.: +45 78 41 01 83 / +45 78 41 01 82 / +45 78 41 01 81
E-mail: komite@rm.dk
Hjemmeside: www.komite.rm.dk

Den Videnskabsetiske Komité for Region Nordjylland Tlf.: +45 97 64 84 40
E-mail: vek@rn.dk
Hjemmeside: www.rn.dk/vek

National Videnskabsetisk Komité
Tlf.: +45 72 21 68 55
E-mail: kontakt@nvk.dk
Hjemmeside: www.nvk.dk

Dette tillæg er udarbejdet af det videnskabsetiske komitésystem og kan vedhæftes den skriftlige information om det sundhedsvidenskabelige forskningsprojekt. Spørgsmål til et konkret projekt skal rettes til projektets forsøgsansvarlige. Generelle spørgsmål til forsøgspersoners rettigheder kan rettes til den komité, som har godkendt projektet.

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Hvidovre
Hospital

SORC-C
Sports Orthopedic Research Center - Copenhagen



Informeret samtykke til deltagelse i videnskabeligt forskningsprojekt

Forskningsprojektets titel:

Effekten af kikkertkirurgi på biomekanik og neuromuskulær kontrol hos patienter med forreste skulderinstabilitet efter traume: Et prospektivt cohortestudie

Erklæring fra forsøgspersonen:

Jeg har fået skriftlig og mundtlig information og jeg ved nok om formål, metode, fordele og ulemper til at sige ja til at deltage.

Jeg ved, at det er frivilligt at deltage, og at jeg altid kan trække mit samtykke tilbage uden videre konsekvenser.

Jeg giver samtykke til, at deltage i forskningsprojektet. Jeg har fået en kopi af dette samtykkeark samt en kopi af den skriftlige information om projektet til eget brug.

Forsøgspersonens navn: _____

Dato: _____ Underskrift: _____

Ønsker du at blive informeret om forskningsprojektets resultat samt eventuelle konsekvenser?:

Ja Nej

Ønsker du at blive informeret om væsentlige oplysninger om din egen helbredstilstand?:

Ja Nej

Erklæring fra den, der afgiver informationen:

Jeg erklærer, at forsøgspersonen har modtaget mundtlig og skriftlig information om forsøget og har haft mulighed for at stille spørgsmål.

Efter min overbevisning er der givet tilstrækkelig information til, at der kan træffes beslutning om deltagelse i forsøget.

Navnet på den, der har afgivet informationen: _____

Dato: _____ Underskrift: _____

Baseline Demographics

Form Status

Subject ID

Gender

- Male
- Female
- Other

Weight, kg w. 1 decimal

(Vægt i kg, med 1 decimal)

Height, cm

(Højde i cm)

BMI

(BMI: vægt/(højde*højde) kg og cm)

Dominant side

- right
- left
- both
- other

If other, explain

Injured shoulder, side

- Right
 - Left
- (Beskadiget skulder, side)

Primary injury mechanism

- Fell on outstretched arm
 - Fell directly on shoulder
 - Arm was pulled
 - External force to shoulder
 - Other
- (Skadesmekanisme)

If 5) other, explain:

(Hvis anden skadesmekanisme, da uddyb)

1 No. dislocations of injured shoulder

2

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No. dislocations of injured shoulder

0

1

2

3

4

5

6-10

11-15

16-20

>20

Only subluxation(s)
(Antal luksationer)

Previous treatment(s) of shoulder instability

Home-based exercise

Supervised exercise (physiotherapy)

Passive treatment (manipulation, massage, acupuncture)

Chiropractor

Pain relievers

Other medicines

Other

(Tidl. forsøgt behandling(er))

If either:
smertestillende medicin
anden medicinsk behandling
anden behandling,
explain:

(Uddyb medicinsk behandling/anden behandling)

Pre-injury activity level. (ADL: bathing, dressing, toileting, transferring (moving to and from a bed or a chair), eating, and continence).

Limited ADL

Unlimited ADL

Physical activity w. affected limb 1-3/w.

Physical activity w. affected limb >3/w.
(Fysisk aktivitet før skade)

Post-injury activity level. (ADL: bathing, dressing, toileting, transferring (moving to and from a bed or a chair), eating, and continence).

Limited ADL

Unlimited ADL

Physical activity w. affected limb 1-3/w.

Physical activity w. affected limb >3/w.
(Fysisk aktivitet efter skade)

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1
2
3
4
5 KLINISK SKULDERUNDERSØGELSE - Bankart
6
7

Marker dominant side	HØ	VE
Inspektion		
Palpation		
Flexion		
Extension		
Abduktion		
IR		
ER		
Hawkins		
Empty can scaption +force		
Jobe's		
Adduction +thumbs up/down		
O'Brien's		
Sulcus test		
Load and shift		
Apprehension		
Relocation		

Denmark Danish Eq5d5l Redcap Self Complete Web

1 Venligst udfyld spørgeskema nedenunder.

2 Tak og mvh

3 Catarina Malmberg, læge og PhD-studerende

4

5 Du bedes klikke med musen i DEN kasse, der bedst beskriver dit helbred I DAG.

6

7 BEVÆGELIGHED

- 8
- 9
- 10
- 11
- 12
- 13 Jeg har ingen problemer med at gå omkring
- 14 Jeg har lidt problemer med at gå omkring
- 15 Jeg har moderate problemer med at gå omkring
- 16 Jeg har store problemer med at gå omkring
- 17 Jeg kan ikke gå omkring

18

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20

21 Du bedes klikke med musen i DEN kasse, der bedst beskriver dit helbred I DAG.

22

23 PERSONLIG PLEJE

- 24
- 25
- 26 Jeg har ingen problemer med at vaske mig eller klæde mig på
- 27 Jeg har lidt problemer med at vaske mig eller klæde mig på
- 28 Jeg har moderate problemer med at vaske mig eller klæde mig på
- 29 Jeg har store problemer med at vaske mig eller klæde mig på
- 30 Jeg kan ikke vaske mig eller klæde mig på

31

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33

34 Du bedes klikke med musen i DEN kasse, der bedst beskriver dit helbred I DAG.

35

36 SÆDVANLIGE AKTIVITETER (fx. arbejde, studie, husarbejde, familie- eller fritidsaktiviteter)

- 37
- 38
- 39 Jeg har ingen problemer med at udføre mine sædvanlige aktiviteter
- 40 Jeg har lidt problemer med at udføre mine sædvanlige aktiviteter
- 41 Jeg har moderate problemer med at udføre mine sædvanlige aktiviteter
- 42 Jeg har store problemer med at udføre mine sædvanlige aktiviteter
- 43 Jeg kan ikke udføre mine sædvanlige aktiviteter

44

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46

47 Du bedes klikke med musen i DEN kasse, der bedst beskriver dit helbred I DAG.

48

49 SMERTER / UBEHAG

- 50
- 51 Jeg har ingen smerter eller ubehag
- 52 Jeg har lidt smerter eller ubehag
- 53 Jeg har moderate smerter eller ubehag
- 54 Jeg har stærke smerter eller ubehag
- 55 Jeg har ekstreme smerter eller ubehag
- 56

57

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59

60 Du bedes klikke med musen i DEN kasse, der bedst beskriver dit helbred I DAG.

1) ANGST / DEPRESSION

- 2)
- 3) Jeg er ikke ængstelig eller deprimeret
- 4) Jeg er lidt ængstelig eller deprimeret
- 5) Jeg er moderat ængstelig eller deprimeret
- 6) Jeg er meget ængstelig eller deprimeret
- 7) Jeg er ekstremt ængstelig eller deprimeret
- 8)

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10)

11) Vi vil gerne vide, hvor godt eller dårligt dit
12) helbred er I DAG.

13)

14) Denne skala er nummereret fra 0 til 100.

15)

16) 100 svarer til det bedste helbred, du kan forestille
17) dig.
18) 0 svarer til det dårligste helbred, du kan forestille
19) dig.
20) Klik med musen på det sted på skalaen, der viser,
21) hvordan dit helbred er I DAG.

22)

0 -
Det dårligste
helbred, du kan
forestille dig



50

100 - Det
bedste helbred,
du kan forestille
dig

(Place a mark on the scale above)

25) © EuroQol Research Foundation. EQ-5D™ is a trade mark of the EuroQol Research Foundation

26)

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Spørgeskema om skulderfunktion (WOSI)

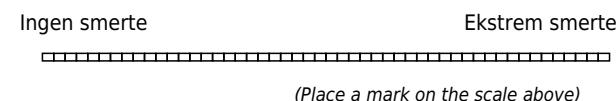
1
2 Kære deltager
3

4 Du bedes venligst at udfylde dette spørgeskema. Det er desværre ikke muligt at gemme undervejs, men hele
5 spørgeskemaet må besvares når du er startet (du kan til gengælg starte forfra, hvis du er nødt til at afbryde).
6

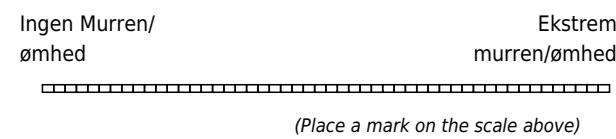
7 Tak for din deltagelse! Mvh projektansvarlige
8
9

10 **Sektion A: De følgende spørgsmål drejer sig om de fysiske symptomer, du har på grund af dit
11 skulderproblem. Ved hvert spørgsmål skal du på linjen markere omfanget af dine symptomer
12 indenfor den seneste uge.**

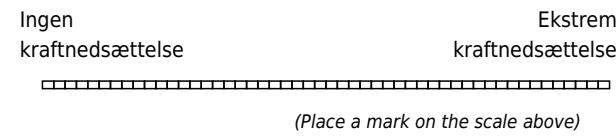
13
14
15 Hvor ondt gør det i din skulder, når du arbejder med
16 armen over hovedet?



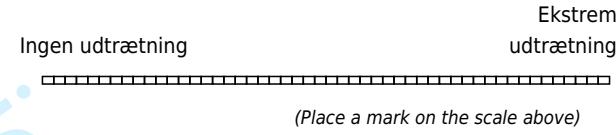
17
18
19 Hvor meget murren eller ømhed har du i skulderen?



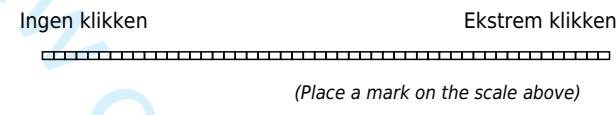
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22 Hvor plaget er du af kraftnedsættelse eller manglende
23 styrke i din skulder?



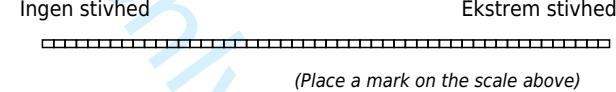
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26 Hvor plaget er du af udtrætning eller manglende
27 udholdenhed i din skulder?



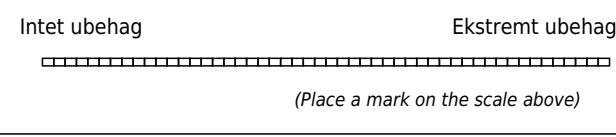
28
29 Hvor generet er du af klikken, knasen eller smæld i
30 skulderen?



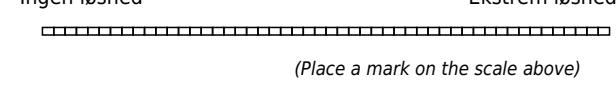
31
32 Hvor generet er du af stivhed i skulderen?



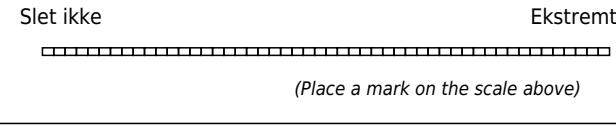
33
34 Hvor meget ubehag har du i dine nakkemuskler som en
35 følge af dit skulderproblem?



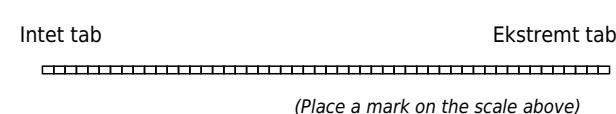
36
37 Hvor ustabil eller løs er din skulder?



38
39 Hvor meget kompenserer du for din skulder med brug af
40 andre muskler?



41
42 Hvor meget har du mistet af din bevægelighed i
43 skulderen?



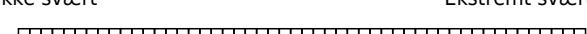
For peer review only - <http://bmjopen.bmj.com/site/about/guidelines.xhtml>

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**Sektion B: Følgende afsnit handler om, hvor meget dit skulderproblem har påvirket dit
5 arbejde, dine sports- og fritidsaktiviteter indenfor den seneste uge. Du skal igen til hvert
6 spørgsmål markere omfanget af dine symptomer på linjen
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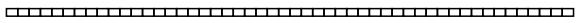
- 11) Hvor meget har dit skulderproblem begrænset dig i at
deltage i sport eller fritidsaktiviteter? Ikke begrænset Begrænset
ekstremt

(Place a mark on the scale above)
- 12) Hvor meget har skulderen indvirket på din evne til at
udføre specifikke færdigheder, som er nødvendige i
din sport eller dit arbejde? (Hvis skulderen generer
både ved arbejde og sport skal du angive det i
forhold til der hvor den generer mest) Ingen indvirkning Ekstrem
indvirkning

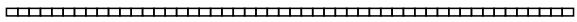
(Place a mark on the scale above)
- 13) Hvor stort et behov har du for at beskytte din arm
under aktivitet? Slet ikke Ekstremt

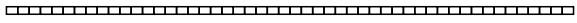
(Place a mark on the scale above)
- 14) Hvor svært er det at løfte tunge ting under
skulderens niveau? Ikke svært Ekstremt svært

(Place a mark on the scale above)

1 **Sektion C: Følgende afsnit handler om, i hvor høj grad dit skulder problem har påvirket eller**
2 **ændret din livsstil. Du skal igen til hvert spørgsmål markere omfanget af dine symptomer på**
3 **linjen**

4
5) Hvor meget frygter du at falde på din skulder? Ingen frygt Ekstrem frygt
6 
7 (Place a mark on the scale above)

8
9) 16) I hvilken grad forhindrer dit skulderproblem dig i at Slet ikke Ekstrem grad
10 holde dig i form? 
11 (Place a mark on the scale above)

12
13) 17) Hvor svært har du ved løssluppen aktivitet, så som Ingen besvær Ekstremt besvær
14 brydning og slåskamp med familie og venner? 
15 (Place a mark on the scale above)

16
17) 18) Hvor meget søvnbesvær har du på grund af din Ingen besvær Ekstremt besvær
18 skulder? 
19 (Place a mark on the scale above)

1 **Sektion D: De følgende spørgsmål handler om, hvordan du har følt det den sidste uge med**
2 **hensyn til dit skulderproblem. Marker omfanget på linjen**

49) Hvor bevidst er du om din skulder?	Ikke bevidst	Ekstrem bevidst
<hr style="border: 1px solid black; width: 80%; margin-left: auto; margin-right: 0;"/> (Place a mark on the scale above)		
<hr style="border: 1px solid black; width: 100%;"/>		
80) Hvor bekymret er du for at dit skulderproblem 9 forværres?	Ikke bekymret	Ekstremt bekymret
<hr style="border: 1px solid black; width: 80%; margin-left: auto; margin-right: 0;"/> (Place a mark on the scale above)		
<hr style="border: 1px solid black; width: 100%;"/>		
21) Hvor frustreret er du over din skulder?	Ikke frustreret	Ekstremt frustreret
<hr style="border: 1px solid black; width: 80%; margin-left: auto; margin-right: 0;"/> (Place a mark on the scale above)		
<hr style="border: 1px solid black; width: 100%;"/>		

1 2 Reporting checklist for protocol of a clinical trial. 3 4 5 6

7 Based on the SPIRIT guidelines.
8
9

10 Instructions to authors 11

12 Complete this checklist by entering the page numbers from your manuscript where readers will find
13 each of the items listed below.
14
15

16 Your article may not currently address all the items on the checklist. Please modify your text to
17 include the missing information. If you are certain that an item does not apply, please write "n/a" and
18 provide a short explanation.
19
20

21 Upload your completed checklist as an extra file when you submit to a journal.
22
23

24 In your methods section, say that you used the SPIRIT reporting guidelines, and cite them as:
25
26

27 Chan A-W, Tetzlaff JM, Gøtzsche PC, Altman DG, Mann H, Berlin J, Dickersin K, Hróbjartsson A,
28 Schulz KF, Parulekar WR, Krleža-Jerić K, Laupacis A, Moher D. SPIRIT 2013 Explanation and
29 Elaboration: Guidance for protocols of clinical trials. BMJ. 2013;346:e7586
30
31

32 Reporting Item

33 Page Number

34 Administrative 35

36 information 37

38 Title

39 #1

40 Descriptive title identifying the study design,
41 population, interventions, and, if applicable, trial
42 acronym
43

44 1 (manuscript)

45 Trial registration

46 #2a

47 Trial identifier and registry name. If not yet registered,
48

49 1 (suppl 1)
50
51

		name of intended registry	
1	Trial registration:	#2b All items from the World Health Organization Trial	1 (suppl 1)
2	data set	Registration Data Set	
3	Protocol version	#3 Date and version identifier	1 (suppl 1)
4	Funding	#4 Sources and types of financial, material, and other	23 (manuscript)
5		support	1-2 (suppl 1)
6	Roles and responsibilities:	#5a Names, affiliations, and roles of protocol contributors	2-4 (suppl 1)
7	contributorship		
8	Roles and responsibilities:	#5b Name and contact information for the trial sponsor	2 (suppl 1)
9	sponsor contact		
10	information		
11	Roles and responsibilities:	#5c Role of study sponsor and funders, if any, in study	23 (manuscript)
12	sponsor and funder	design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	1-2 (suppl 1)
13	Roles and responsibilities:	#5d Composition, roles, and responsibilities of the	n/a
14	committees	coordinating centre, steering committee, endpoint adjudication committee, data management team, and	

other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)

Introduction

Background and rationale **#6a** Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention

Background and rationale: choice of comparators **#6b** Explanation for choice of comparators

Objectives **#7** Specific objectives or hypotheses

Trial design **#8** Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, non-inferiority, exploratory)

Methods:

Participants, interventions, and outcomes

Study setting **#9** Description of study settings (eg, community clinic, academic hospital) and list of countries where data

4-6

(manuscript)

7 (manuscript)

6-7 (manuscript)

7 (manuscript)

10

(manuscript), 4

1 will be collected. Reference to where list of study sites
 2 can be obtained

3
 4 Eligibility criteria #10 Inclusion and exclusion criteria for participants. If
 5 applicable, eligibility criteria for study centres and
 6 individuals who will perform the interventions (eg,
 7 surgeons, psychotherapists)

10-11

(manuscript)

8
 9 Interventions: #11a Interventions for each group with sufficient detail to
 10 allow replication, including how and when they will be
 11 administered

7-12

(manuscript)

12
 13 Interventions: #11b Criteria for discontinuing or modifying allocated
 14 interventions for a given trial participant (eg, drug
 15 dose change in response to harms, participant
 16 request, or improving / worsening disease)

11, 13-15

(manuscript)

17
 18 Interventions: #11c Strategies to improve adherence to intervention
 19 protocols, and any procedures for monitoring
 20 adherence (eg, drug tablet return; laboratory tests)

n/a

21
 22 Interventions: #11d Relevant concomitant care and interventions that are
 23 permitted or prohibited during the trial

11

(manuscript)

24
 25 Outcomes #12 Primary, secondary, and other outcomes, including
 26 the specific measurement variable (eg, systolic blood
 27 pressure), analysis metric (eg, change from baseline,
 28 final value, time to event), method of aggregation (eg,
 29 median, proportion), and time point for each outcome.
 30 Explanation of the clinical relevance of chosen

7-12

(manuscript)

1	2	3	4	5	efficacy and harm outcomes is strongly recommended	
6	Participant timeline	#13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	12	(manuscript)	
7	8	9	10	11	12	13
14	Sample size	#14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	12-13	(manuscript)	
15	16	17	18	19	20	21
22	Recruitment	#15	Strategies for achieving adequate participant enrolment to reach target sample size	10	(manuscript)	
23	24	25	26	27	28	29
31	Methods:					
32	Assignment of					
33	interventions (for					
34	controlled trials)					
35	Allocation: sequence	#16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	n/a		
36	generation					
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58	Allocation	#16b	Mechanism of implementing the allocation sequence	n/a		
59						
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1	concealment	(eg, central telephone; sequentially numbered,
2	mechanism	opaque, sealed envelopes), describing any steps to
3		conceal the sequence until interventions are assigned
4		
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7		
8	Allocation:	#16c Who will generate the allocation sequence, who will
9	implementation	enrol participants, and who will assign participants to
10		interventions
11		
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16	Blinding (masking)	#17a Who will be blinded after assignment to interventions
17		(eg, trial participants, care providers, outcome
18		assessors, data analysts), and how
19		
20		
21		
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23	Blinding (masking):	#17b If blinded, circumstances under which unblinding is
24	emergency	permissible, and procedure for revealing a
25		participant's allocated intervention during the trial
26		
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31	Methods: Data	
32		
33	collection,	
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35	management, and	
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37	analysis	
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41	Data collection plan	#18a Plans for assessment and collection of outcome,
42		baseline, and other trial data, including any related
43		processes to promote data quality (eg, duplicate
44		measurements, training of assessors) and a
45		description of study instruments (eg, questionnaires,
46		laboratory tests) along with their reliability and validity,
47		if known. Reference to where data collection forms
48		can be found, if not in the protocol
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1	Data collection plan:	#18b	Plans to promote participant retention and complete retention follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	11 (manuscript)
11	Data management	#19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	15-16 (manuscript)
25	Statistics: outcomes	#20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	13 (manuscript)
35	Statistics: additional analyses	#20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	n/a
41	Statistics: analysis population and missing data	#20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	11 (manuscript)
51	Methods: Monitoring			
54	Data monitoring: formal committee	#21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement	n/a

of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed

12 Data monitoring:
13 **#21b** Description of any interim analyses and stopping
14 interim analysis
15 guidelines, including who will have access to these
16 interim results and make the final decision to
17 terminate the trial

22 Harms
23 **#22** Plans for collecting, assessing, reporting, and
24 managing solicited and spontaneously reported
25 adverse events and other unintended effects of trial
26 interventions or trial conduct

32 Auditing
33 **#23** Frequency and procedures for auditing trial conduct, if
34 any, and whether the process will be independent
35 from investigators and the sponsor

40 Ethics and 41 dissemination

45 Research ethics
46 **#24** Plans for seeking research ethics committee /
47 institutional review board (REC / IRB) approval

16, 18

(manuscript), 1 (suppl 1)

53 Protocol
54 amendments
55 **#25** Plans for communicating important protocol
56 modifications (eg, changes to eligibility criteria,
57 outcomes, analyses) to relevant parties (eg,

2 (suppl 1)

1	2	3	4	5	investigators, REC / IRBs, trial participants, trial registries, journals, regulators)	10
6	Consent or assent	#26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	(manuscript), 2-3 (suppl 1)	11	12
13	Consent or assent: ancillary studies	#26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	n/a	14	15
16	Confidentiality	#27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	(manuscript)	17	18
19	Declaration of interests	#28	Financial and other competing interests for principal investigators for the overall trial and each study site	16 23 (manuscript), 1-2 (suppl 1)	20	21
22	Data access	#29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	11, 16 (manuscript)	23	24
25	Ancillary and post trial care	#30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	2 (suppl 1)	26	27
28	Dissemination policy: trial results	#31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals,	16-17 (manuscript)	29	30

the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions

10 Dissemination **#31b** Authorship eligibility guidelines and any intended use
11 policy: authorship of professional writers
12 (manuscript)

13 Dissemination **#31c** Plans, if any, for granting public access to the full
14 policy: reproducible protocol, participant-level dataset, and statistical code
15 (manuscript)
16 research
17
18

23 Appendices 24

25 Informed consent **#32** Model consent form and other related documentation
26 materials given to participants and authorised surrogates
27
28

29 Biological **#33** Plans for collection, laboratory evaluation, and
30 specimens storage of biological specimens for genetic or
31 molecular analysis in the current trial and for future
32 use in ancillary studies, if applicable
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41 Notes: 42

- 43 • 1: 1 (manuscript)
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- 45 • 2a: 1 (suppl 1)
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- 47 • 2b: 1 (suppl 1)
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- 6 • 5c: 23 (manuscript), 1-2 (suppl 1)
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- 17 • 9: 10 (manuscript), 4 (suppl 1)
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- 19 • 10: 10-11 (manuscript)
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- 21 • 11a: 7-12 (manuscript)
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- 23 • 11b: 11, 13-15 (manuscript)
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- 25 • 11d: 11 (manuscript)
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- 1 • 20a: 13 (manuscript)
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- 31 • 30: 2 (suppl 1)
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- 34 • 31a: 16-17 (manuscript)
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- 37 • 31b: 17 (manuscript)
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- 40 • 31c: 18 (manuscript) The SPIRIT Explanation and Elaboration paper is distributed under the
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- 42
- 43 20. July 2023 using <https://www.goodreports.org/>, a tool made by the [EQUATOR Network](#) in
- 44
- 45 collaboration with [Penelope.ai](#)
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BMJ Open

Biomechanical and Neuromuscular Characteristics in Patients with Traumatic Anterior Shoulder Instability Undergoing Arthroscopic Bankart Repair: A Clinical Prospective Cohort Study Protocol

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2023-078376.R1
Article Type:	Protocol
Date Submitted by the Author:	04-Dec-2023
Complete List of Authors:	Malmberg, Catarina; Hvidovre Hospital Sports Orthopedic Research Center Copenhagen, Dept. of Orthopedic Surgery Andreasen, Kristine; Hvidovre Hospital Sports Orthopedic Research Center Copenhagen, Dept. of Orthopedic Surgery Bencke, Jesper; Copenhagen University Hospital, Human Movement Analysis Laboratory Kjær, Birgitte; Institute of Sports Medicine, Department of Physical and Occupational Therapy Hølmich, Per; Hvidovre Hospital Sports Orthopedic Research Center Copenhagen, Dept. of Orthopedic Surgery Barfod, KW; Hvidovre Hospital Sports Orthopedic Research Center Copenhagen, Dept. of Orthopedic Surgery
Primary Subject Heading:	Sports and exercise medicine
Secondary Subject Heading:	Surgery
Keywords:	Shoulder < ORTHOPAEDIC & TRAUMA SURGERY, Orthopaedic sports trauma < ORTHOPAEDIC & TRAUMA SURGERY, Musculoskeletal disorders < ORTHOPAEDIC & TRAUMA SURGERY, Observational Study, Orthopaedic & trauma surgery < SURGERY, Elbow & shoulder < ORTHOPAEDIC & TRAUMA SURGERY

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1 Biomechanical and Neuromuscular Characteristics in Patients with Traumatic 2 Anterior Shoulder Instability Undergoing Arthroscopic Bankart Repair: A 3 Clinical Prospective Cohort Study Protocol

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5 Hougs Kjær³, MSc PhD, Per Hölmich¹, MD DMSc, Kristoffer Weisskirchner Barfod¹, MD PhD

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11 (ISM), Copenhagen University Hospital Bispebjerg & Frederiksberg

12 Corresponding author: Catarina Malmberg, Kettegård Allé 30, 2650 Hvidovre,
13 catarina.anna.evelina.malmberg.02@regionh.dk

14 Competing interests: None

15 Word count abstract: 250

16 Word count manuscript: 4223

1
2
3
4 **17 Abstract**
5
6 **18 Introduction:** Traumatic shoulder dislocation is a common shoulder injury, especially among the
7
8 **19 young and active population.** More than 95% of dislocations are anterior, in which the humeral head
9
10 **20 is forced beyond the anterior glenoid rim.** The injury leads to increased joint laxity and recurrence
11
12 **21 rates are high.** There is evidence that the shoulder biomechanics and neuromuscular control change
13
14 **22 following dislocation,** but the existing literature is scarce, and it remains to be established if and
15
16 **23 how these parameters are useful in the clinical setting.** The aim of this exploratory prospective
17
18 **24 cohort study** is to investigate biomechanical and neuromuscular outcomes in patients with traumatic
19
20 **25 anterior shoulder instability undergoing arthroscopic Bankart repair,** to test the hypothesis that
21
22 **26 examinations of these characteristics are applicable in the clinical setting to assess shoulder**
23
24 **27 instability.**

28
29 **30 Methods and analysis:** This is a prospective multicenter cohort study with repeated measures of 55
31
32 **33 patients undergoing arthroscopic Bankart repair.** With carefully selected and completely non-
33
34 **35 invasive examination methods,** we will investigate biomechanical and neuromuscular outcomes in
36
37 **38 the affected shoulders once pre-surgically and twice post-surgically at six and twelve months.**

39 **40 Patients' contralateral shoulders are investigated once to establish a pre-injury level.**

41
42 **43 Ethics and dissemination:** The study was approved by the Capital Region Ethics Committee
43
44 **45 (journal-no: H-21027799) and the Capital Region Knowledge Center for Data Reviews (journal-no:**
46
47 **48 P-2021-842)** before patient recruitment began. The study results will be published in international
48
49 **50 peer-reviewed journals, online and in other relevant media, presented at medical conventions and**
50
51 **52 disseminated to clinicians and patients as appropriate.**

53
54 **55 Trial registration number:** NCT05250388
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4 39 Keywords: traumatic shoulder instability, anterior shoulder instability, biomechanics, kinematics,
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6 40 proprioception, neuromuscular control, arthroscopic Bankart repair
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For peer review only

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4 41 **Strengths and limitations**
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6 42 • This study has a broad investigation approach including biomechanical, neuromuscular, clinical,
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8 43 and patient-centered examinations and outcomes.
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10 44 • All examination methods are non-invasive.
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12 45 • The study is essentially exploratory, as the literature on biomechanical and neuromuscular
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14 46 changes in patients with traumatic shoulder instability is scarce and the authors cannot refer to
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16 47 any established standard deviations or minimally important difference.
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48 1. Introduction

49 1.1 Background

50 Traumatic anterior shoulder dislocation is a common shoulder injury, with a reported point
10 prevalence of 1.7% in a general population aged 18-70 years and incidence rates of 11.2-56.3 per
11 51 100'000 person years [1-3]. First-time dislocation incidence rates are highest in the third decade of
12 52 life for men, while it is most common in women above 50 years of age [3] The injury causes an
13 53 increased glenohumeral joint laxity and recurrence rates exceed 70% in some reports [4]. Besides
14 54 disruption and injury to the capsule, labrum and ligaments, bone loss is often seen after the injury
15 55 [5]. The bone loss can be isolated to the anteroinferior part of the glenoid, referred to either as the
16 56 osseous Bankart lesion or a glenoid rim erosion, or to the posterolateral aspect of the humeral head,
17 57 the Hill-Sachs lesion, but can also be seen in combination as bipolar lesions, creating an additive
18 58 negative effect on the joint laxity [6]. Thus, the extent of the structural injury plays a role in
19 59 development of glenohumeral instability.

34 61 Chronic shoulder instability may appear even after the first dislocation and often aggravates with
35 62 recurrence, which can lead to altered shoulder biomechanics and motion control [5,7-9]. The joint
36 63 stability is clinically assessed using manual tests including the sulcus sign, load and shift,
37 64 apprehension test, and relocation test; some of which have high specificity, but are highly patient-
38 65 and examiner-dependent and none of them provide quantitative data [10]. The laxity can be
39 66 directly inspected and quantified during arthroscopy, which is an invasive procedure, or through
40 67 medical imaging methods, which might be irradiating and, furthermore, only examines the joint in a
41 68 static position [6,7,11]. Alternatively, non-invasive and non-irradiating dynamic analysis of the
42 69 shoulder biomechanics can be performed using motion capture and ultrasound [9,12-14].

43 70 Neuromuscular joint control is most often assessed as joint position sense (JPS) or threshold to
44 71 detection of motion (TTDM). In 2015, a systematic review concluded that patients suffering from

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4 72 traumatic anterior shoulder instability had decreased JPS and increased TTDM, thus impaired
5
6 73 neuromuscular joint control compared to those with stable shoulders [15]. Both modalities have
7
8 74 been criticized for the lack of ecological validity, as they are static and without application of an
9
10 75 external force and thereby cannot be generalized to a real-life setting [16]. The shoulder-sway test,
11
12 76 developed in 2012, investigates neuromuscular joint control in a loaded static position [17].
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14 77 Reduced joint control, measured as increased sway-length, has been reported in shoulders with
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16 78 traumatic anterior instability compared to stable, which supports the theory of impaired
17
18 79 neuromuscular control in these patients [18].
19
20 80 In treatment of traumatic anterior shoulder instability, the focus is on restoring stability. Surgically,
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22 81 the structural stability is re-established, and the extent of injury determines the type of surgery [6].
23
24 82 Surgery reduces risk of recurrent events but does not always relieve patients of symptoms. Some
25
26 83 patients still experience a feeling of instability – apprehension – after surgery and suffer from
27
28 84 residual pain and reduced activity level and quality of life [9,19,20]. As the pathologic mechanism
29
30 85 of apprehension is complex and probably includes both mechanical and neurological impairments,
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32 86 the effect of surgery might be questioned [21]. More specifically, the effects on biomechanical and
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34 87 neuromuscular characteristics remain unclear [9,22].
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42 88 1.2 Research questions

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44 89 A (biomechanics): Does arthroscopic Bankart repair have a stabilizing effect on the biomechanics
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46 90 in patients with traumatic anterior shoulder instability?
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50 91 B (neuromuscular control): Does arthroscopic Bankart repair improve neuromuscular control in
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52 92 patients with traumatic anterior shoulder instability?
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4 93 **1.3 Aim**
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6 94 To investigate the effect of arthroscopic Bankart repair on shoulder biomechanics and
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8 95 neuromuscular control and increase understanding of traumatic anterior shoulder instability.
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12 96 **1.4 Objectives and hypotheses**
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14 97 **1.4.1 Objectives research question A**
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16 98 In patients with traumatic anterior shoulder instability undergoing arthroscopic Bankart repair, to
17
18 99 investigate the anterior-posterior glenohumeral translation and the scapular rotations before and six
19
20 100 and twelve months after surgery and whether the ranges are restored to the same as the non-injured
21
22 101 contralateral shoulder.
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27 102 **1.4.2 Hypotheses research question A**
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29 103 1) Arthroscopic Bankart repair results in a ≥ 2.5 mm decrease in anterior-posterior glenohumeral
30
31 104 translation, remaining both six and twelve months after surgery.
32
33 105 2) Arthroscopic Bankart repair reduces anterior-posterior glenohumeral translation to the same
34
35 106 range as measured in the non-injured shoulder (± 2.5 mm).
36
37 107 3) Arthroscopic Bankart repair reduces superior-inferior glenohumeral translation significantly, as
38
39 108 measured six and twelve months after surgery.
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42 109 4) Scapular rotations and tilt remain unchanged after arthroscopic Bankart repair.
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47 110 **1.4.3 Objectives research question B**
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49 111 In patients with traumatic anterior shoulder instability undergoing arthroscopic Bankart repair, to
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51 112 investigate the neuromuscular control before and six and twelve months after surgery and whether
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53 113 the neuromuscular control is restored to the same level as the non-injured contralateral shoulder.
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57 114 **1.4.4 Hypotheses research question B**
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4 115 1) Arthroscopic Bankart repair improves neuromuscular control, remaining both six and twelve
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7 116 months after surgery.

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9 117 2) Arthroscopic Bankart repair improves neuromuscular control to the same range as the non-
10
11 118 injured shoulder.

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15 119 **1.4.5 Other objectives**

16
17 120 In patients with traumatic anterior shoulder instability undergoing arthroscopic Bankart repair:

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19 121 1) To determine the recurrence rates (radiographically confirmed or manually reduced dislocation)
20
21 122 in the first twelve months after surgery.

22
23 123 2) To investigate the shoulder range of motion (ROM) before and six and twelve months after
24
25 124 surgery.

26
27 125 3) To assess the joint instability by manual testing before and six and twelve months after surgery.

28
29 126 4) To quantify potential bone loss before surgery.

30
31 127 5) To investigate patient-reported outcome measures (PROM) before and six and twelve months
32
33 128 after surgery.

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35 129 6) To investigate if there are correlations between a) the shoulder biomechanics and b) the
36
37 130 neuromuscular control, and PROM, ROM, and bone loss, respectively.

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40 131 **2. Methods and analysis**

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42 132 **2.1 Study design**

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44 133 This is a prospective observational cohort study with repeated measures of the patient's affected
45
46 134 shoulder pre- and post-intervention. The contralateral shoulder is investigated prior to surgery to
47
48 135 establish a pre-injury level representing the non-injured shoulder.

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50 136 **2.2 Outcomes**

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4 137 The outcomes were designed to investigate the effects of arthroscopic Bankart repair on
5 biomechanical and neuromuscular characteristics and, further, to investigate correlations with
6 clinical and patient-centered outcomes (Fig. 1). The change in anterior-posterior glenohumeral
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9 139 translation was chosen as the primary outcome to allow for a statistic sample size calculation (see
10 section 3.1).
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17 142 **2.2.1 Biomechanical outcomes**
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19 143 The primary outcome is the change in anterior-posterior glenohumeral translation six months after
20 surgery as assessed from real-time ultrasound imaging. The examination strictly follows a
21 previously tested protocol in which the joint is tested in two positions: 1) neutral along the body
22 (posterior view) and 2) in abduction and external rotation (anterior view); under three conditions: 1)
23
24 145 previously tested protocol in which the joint is tested in two positions: 1) neutral along the body
25 (posterior view) and 2) in abduction and external rotation (anterior view); under three conditions: 1)
26 146 (posterior view) and 2) during isometric force and 3) with external force applied to the relaxed joint [14,23]. The
27
28 147 at rest, 2) during isometric force and 3) with external force applied to the relaxed joint [14,23]. The
29
30 148 translation, in millimeters, is calculated by subtracting the distance between the border of the
31
32 149 glenoid (posterior view) or the coracoid process (anterior view), respectively, and the border of the
33
34 150 humeral head at rest (condition 1) from the conditions with force applied (conditions 2 and 3). The
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36 151 intra- and interrater reliability of the ultrasound assessment has previously been shown good to
37
38 152 excellent in the abducted position from an anterior view (ICC 0.95-0.96 and 0.72-0.8, respectively)
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40 153 and posterior view (ICC 0.98 and 0.77-0.85, respectively) [24]. The intra- and interrater reliability
41
42 154 with the shoulder in neutral position has also previously been shown to be moderate to excellent
43
44 155 (ICC 0.85-0.98 and 0.5-0.75, respectively) [14]. All ultrasound examinations are carried out by the
45
46 156 same investigator. The change in the anterior-posterior glenohumeral translation is also evaluated
47
48 157 twelve months after surgery (same methods as above).
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54 158 The scapular upward downward rotations, protraction-retraction and anterior-posterior tilt are
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56 159 analyzed using motion capture technique with a skin-marker based protocol and eight cameras
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4 160 simultaneously collecting data during ROM activities and used to evaluate the effect of Bankart
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6 161 repair six and twelve months following surgery. The motion capture protocol was developed in the
7
8 162 Human Movement Analysis Laboratory at Copenhagen University Hospital Hvidovre and has been
9
10 163 previously found to have a mean error of <7° in all scapular rotations and at least moderate
11
12 164 interrater reliability (ICC(2,1) >0,5) for the tested motion tasks in subjects without shoulder
13
14 165 complaints (article in preparation).
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19 166 **2.2.2 Neuromuscular outcomes**
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21 167 The change in neuromuscular control is assessed using the newly developed CANCUS test protocol
22
23 168 at six and twelve months after surgery. The test series includes assessment of the shoulder joint
24
25 169 reaction time, sway, and joint position sense using motion capture, force platforms and surface
26
27 170 electromyography (EMG). The shoulder reaction time test determines the neuromuscular control in
28
29 171 a loaded and fast dynamic setting. It was developed at the Human Movement Analysis Laboratory
30
31 172 at Copenhagen University Hospital Hvidovre and is currently being tested in subjects without
32
33 173 shoulder complaints and in subjects with unilateral recurrent anterior shoulder instability. The sway
34
35 174 test determines the neuromuscular control in a weightbearing and static position, using force
36
37 175 platforms to determine the center of pressure in the frontal and sagittal planes. The joint position
38
39 176 sense is a slow dynamic, non-weightbearing evaluation of how precisely the patient can reproduce a
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41 177 given position of the joint. It is tested in an external rotational motion with the arm in 90°
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50 179 **2.2.3 Clinical and patient-reported outcomes**
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52 180 Demographic parameters including age, gender, height, weight, limb dominance, pre-injury and
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54 181 current physical activity level, the initial mechanism of injury, number of dislocations and previous
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56 182 non-surgical treatment will be collected (Supplement 1).
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4 183 Any radiographically confirmed or manually reduced dislocations in the first twelve months are
5 registered during follow-up. Further, the active shoulder ROM (flexion, extension, abduction,
6 internal and external rotation) is evaluated using a handheld goniometer before and six and twelve
7 months after surgery. The clinical instability tests sulcus sign, load and shift, apprehension test and
8 relocation test are performed and evaluated with dichotomous outcomes at all three visits
9 186 (positive/negative). The sulcus sign is considered positive if a sulcus (>1 cm) appears in the
10 subacromial region when manual inferior traction to a neutral shoulder is applied. The load and shift
11 test is considered positive when there is increased anterior-posterior laxity with a sensation of
12 subluxation of the humeral head anteriorly AND there is a clear asymmetry compared to the
13 contralateral as the upper arm is anteriorly translated. The apprehension test and relocation test is
14 performed with the patient lying supine and the shoulder positioned in 90 degrees abduction and
15 externally rotated, and considered positive if an anteriorly directed pressure to the upper arm leads
16 to a sensation of discomfort or instability which is relieved when the arm is pushed posteriorly. The
17 manual tests are performed by the same investigator.
18 196 All patients undergo a pre-surgical computed tomography (CT) scan to measure potential bone loss.
19 197 Glenoid bone loss is measured using the PICO-method, which is based on calculating the size of the
20 defect as the percentage of a best-fit circle from the contralateral glenoid [25]. The size (the largest
21 height, width and depth in millimeters) of Hill-Sachs lesions on the humeral head is also measured
22 and registered, but not the specific location [26].
23 202 The perceived change in shoulder function is evaluated using the Western Ontario Shoulder
24 Instability (WOSI) index [27]. It consists of 21 items, each scored on a 100 mm Visual Analogue
25 Scale (VAS). Each item falls into one of the domains of physical function, sports/recreation/work,
26 lifestyle, and emotional well-being. Each question is scored between 0-100 points and the sum of all
27 206 the questions adds up to a final score, ranging from 0 (best) to 2100 (worst).
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4 207 The perceived change in quality of life is assessed using the EQ-5D questionnaire, which has five
5 components that assess the severity of problems in three functional dimensions (mobility, self-care
6
7 208 and usual activities) and two somatic symptom dimensions (pain/discomfort and
8
9 209 anxiety/depression) [28]. The response scales consist of a heading and five short statements, each
10
11 210 describing a different level of severity.
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17 212 **2.3 Study setting**
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19 213 The patients are screened for eligibility and treated at five centers specialized in treatment of
20 shoulder instability. The centers include the Department of Orthopedic Surgery, Copenhagen
21 University Hospital Amager & Hvidovre, the Department of Orthopedic Surgery, Copenhagen
22
23 215 University Hospital Herlev & Gentofte, the Department of Orthopedic Surgery, Zealand University
24
25 216 University Hospital Køge, Adeas Hospital, Gildhøj Private Hospital. The final enrolment in the study and all
26
27 217 study-related investigations are performed at Copenhagen University Hospital Hvidovre. All data
28
29 218 collection (collection of informed consent, clinical examination, biomechanical and neuromuscular
30
31 219 examinations, CT scan, and collection of PROMs are performed at Copenhagen University Hospital
32
33 220 Hvidovre. See Supplement 2 for further general information.
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41 222 **2.4 Study population and eligibility criteria**
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43 223 Fifty-five patients with traumatic anterior shoulder instability undergoing arthroscopic Bankart
44 repair will be recruited from the centers listed above.
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46 224 Eligibility criteria are age 18-40 years, unilateral traumatic anterior shoulder instability following
47 radiographically confirmed or manually reduced dislocation (first-time or recurrent), scheduled for
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49 225 arthroscopic Bankart repair, no pathology in the contralateral shoulder, willingness to adhere to the
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51 226 study protocol, and ability to give informed consent.
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4 229 Exclusion criteria are other present or previous traumatic pathology or associated injuries in the
5 affected shoulder (including rotator cuff/biceps tendon/SLAP lesion, fracture of proximal
6 humerus/scapula/clavicula, dislocation of sternoclavicular or acromioclavicular joint confirmed by
7 medical imaging), atraumatic pathologies (frozen shoulder, symptomatic osteoarthritis of the
8 shoulder or acromioclavicular joints, acute calcific tendinitis, degenerative rotator cuff tear or
9 neurological disorders), pregnancy, and severe medical illness (American Society of
10 Anesthesiology physical status (ASA) score ≥ 3).
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17 236 All patients must provide written, informed consent prior to any study procedure (Supplement 3).
18 237 The consent gives the primary investigator and relevant authorities access to the patient's records,
19 including electronic medical records and audit, hereunder internal audit, and quality assessment,
20 which are mandatory. The right to access the patient's records is in accordance with the Regional
21 Committee on Health Research Ethics law (§ 3, section 3) and promulgation § 4, section 1, and §
22 240
23 241 10, sections 3 and 5).
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30 242 Study inclusion does not influence the treatment course, neither does a decision to withdraw from
31 the study at any point. Some patients will have a pre-surgical magnetic resonance imaging (MRI)
32 243
33 scan as part of the local practice, which is not required for study inclusion and the results from such
34 a scan will not be used in the study. A patient may be excluded from the study based on the
35 244
36 investigator's decision, e.g., in the event of post-surgical complications (infection, nerve injury,
37 245
38 recurrent event, or revision surgery), as these might influence the post-surgical treatment course and
39 246
40 outcomes, or inability to adhere to the study protocol. Participants may also be excluded if the study
41 247
42 sponsor or government or regulatory authorities terminate the study prior to its planned end date.
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45 250 Patients lost to follow-up are not excluded from analysis but will be specifically accounted for in
46 the report.
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4 252 **2.5 Study plan**

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6 253 There are three visits in total: 1) baseline pre-surgical visit; 2) six months post-surgical ±2 weeks; 3)
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8 254 12 months post-surgical ±2 weeks. All patients undergo arthroscopic Bankart repair at the center
9
10 255 from which they are recruited by an orthopedic surgeon specialized in arthroscopic shoulder
11
12 256 surgery. The procedure is done through a posterior viewing portal and a low antero-lateral portal for
13
14 257 instrumentation. The labrum is released from the glenoid and the bone is scarified. No standard
15
16 258 capsular shift is performed unless deemed necessary by the operating surgeon. Three to four
17
18 259 anchors of the preference of the operating surgeon are placed at the glenoid rim and the labrum is
19
20 260 sutured with simple circular sutures. Surgical details are registered using a standardized form
21
22 261 including the position and extent of the lesion, number and position of anchors used, and whether a
23
24 262 capsular shift was performed is filled out by the surgeon. All patients follow a standardized post-
25
26 263 surgical rehabilitation protocol for a minimum of twelve weeks. All study-related activities are
27
28 264 carried out according to the study plan presented in Table 1.

34 35 Study plan	36 Recruitment	37 Inclusion	38 Pre-surgical visit	39 6 months after surgery	40 12 months after surgery
41 Setting	42 Recruiting center	43	44 Copenhagen University Hospital Hvidovre	45	46
47 Eligibility screen	48 X	49	50	51	52
53 Oral and written study information and enrolment	54	55 X	56	57	58
59 Written informed consent	60	61 X	62	63	64
65 Biomechanical outcomes	66	67	68 X	69 X	70 X
71 Neuromuscular outcomes	72	73	74 X	75 X	76 X
77 Clinical and patient-reported outcomes	78	79	80 X*	81 X	82 X
83 *Computed tomography scan only at pre-surgical visit	84	85	86	87	88

51 265 **Table 1.** Study plan

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54 266 **2.6 Patient and public involvement**

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56 267 Patients with traumatic anterior shoulder instability have not been involved in formulating the
57
58 268 research questions or choosing the outcome measures. However, they were involved in design of

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4 269 the examination methods and protocols used in the study. We carefully assess the burden of all
5 examinations on patients' physical and mental health throughout the study period. The primary
6
7 270 findings will be communicated to the participants.
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12 272 **2.7 Statistics**
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15 273 **2.7.1 Sample size calculation**
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17 274 Fifty-five patients will be included in the study, who will each participate with their contralateral
18 shoulder as non-injured control. The sample size calculation is based on the primary outcome, set to
19 detect a mean difference in anterior-posterior glenohumeral translation of ≥ 2.5 mm, with a standard
20 deviation (SD) of 2.3 mm, power of 0.80 (two-sided) and type I error rate of 0.05 for a mixed
21 effects model [9,29]. With six variables in the analysis (sex, height, BMI, dominant/non-dominant
22 side affected, bone loss, clinical score) and an estimated 15% dropout rate, the calculation resulted
23 in 55 patients.
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34 281 **2.7.2 Statistical analysis**
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36 282 Descriptive statistics will be presented as mean (SD), median (range), and percentages with 95%
37 confidence intervals as considered appropriate. Normality of data distribution will be tested, and
38 relevant statistics applied. Results will be evaluated on group level (injured/non-injured shoulder).
39
40 284
41 285 If data are normally distributed the primary analysis on baseline data will be a linear regression
42 model stratified for sex and height. Correspondingly, the primary analysis including data after
43
44 286 intervention will be a mixed effect model with the variables: sex, height, BMI, dominant/non-
45 dominant side affected, bone loss, and clinical score. If necessary, other relevant statistic models
46
47 288 will be chosen according to the characteristics and distribution of the variables. Patients lost to
48 intervention will be included in the analysis. Prior to any analysis, missing data pattern will be
49
50 289 investigated and reasons for missing data obtained and summarized where possible. The primary
51
52 290 follow up are not excluded from the analysis. Prior to any analysis, missing data pattern will be
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54 291 investigated and reasons for missing data obtained and summarized where possible. The primary
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4 292 analysis will be conducted as an intention-to-treat analysis, which includes all participants with
5 missing outcome data, unless there is clear evidence that its underlying assumption is inappropriate.
6
7 293 The main comparisons planned for the biomechanical, neuromuscular, clinical, and patient-centered
8 outcomes are shown in Table 2.
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Outcome	Comparisons
Biomechanical	<ol style="list-style-type: none"> Change in anterior-posterior glenohumeral translation from baseline to six months (primary outcome), and twelve months. Change in superior-inferior glenohumeral translation from baseline to six and twelve months. Change in scapular upward downward rotations, protraction-retraction and anterior-posterior tilt from baseline to six and twelve months. Side to side difference between the injured and the non-injured shoulder in anterior-posterior glenohumeral translation at baseline, and six and twelve months. Side to side difference between the injured and the non-injured shoulder in scapular upward downward rotations, protraction-retraction and anterior-posterior tilt at baseline, and six and twelve months.
Neuromuscular <i>(the analyses are considered exploratory with no hierarchy between the outcomes)</i>	<ol style="list-style-type: none"> Change in reaction time from baseline to six and twelve months. Change in sway length from baseline to six and twelve months. Change in joint position sense from baseline to six and twelve months. Side to side difference between the injured and the non-injured shoulder in reaction time, sway, and joint position sense at baseline, and six and twelve months.
Clinical and patient reported outcomes <i>(the analyses are considered exploratory with no hierarchy between the outcomes)</i>	<ol style="list-style-type: none"> Correlations with biomechanical and neuromuscular outcomes Change in WOSI index from baseline to six and twelve months. Change in EQ-5D questionnaire from baseline to six and twelve months. Change in range of motion from baseline to six and twelve months. Correlations between bone-loss and WOSI index, EQ-5D questionnaire, re-dislocation, and range of motion.

49 296 **Table 2.** Main comparisons for the biomechanical, neuromuscular, clinical, and patient-centered
50 outcomes. WOSI: Western Ontario Shoulder Instability index.
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4 298 **3. Ethics and dissemination**
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7 299 **3.1 Quality**
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9 300 The validity and inter-rater reliability of the motion capture model for analysis of scapular rotations
10
11 301 were established by the research group prior to study start. The reliability of the ultrasound
12
13
14 302 technique has a reported test-retest measurement error of 0.2-0.6 mm [30]. For the CANCUS test
15
16 303 series, the construct validity and intra-rater reliability of each test is established concurrently during
17
18 304 the study. The demographics and clinical examination sheet, as well as PROM questionnaires can
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20
21 305 be found in Supplement 1 (clinical examination sheet and PROM questionnaires in Danish).
22
23

24 306 **3.2 Risks, side effects and adverse events**
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26 307 The clinical examination and manual tests are clinical practice and not considered to be a risk for
27
28 308 the participants. The motion capture model and ultrasound technique are non-invasive and not
29
30
31 309 considered to induce any discomfort during the tests. When removing the skin-mounted markers
32
33 310 following motion capture and EMG investigations the patient might experience slight discomfort
34
35 311 from the pull on the skin and possible loss of hair, like removal of a band-aid. Some people might
36
37 312 have a temporary redness on the skin, which might be eased with normal body lotion. The arm
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40 313 movements included in the experiment does not exceed normal functional use of the upper limb but
41
42 314 might induce apprehension of short duration. As for the assessment of neuromuscular control a
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45 315 transient discomfort during the tests is expected with increasing stress on the glenohumeral joint.
46
47 316 Before each test, the ROM of the patient is tested and is not exceeded. If the patient cannot achieve
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49 317 the ROM required for the test to be carried out, the patient is excluded from the specific test.
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51 318 The radiation acquired during a diagnostic shoulder CT scan with the scanners that are currently
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53
54 319 operating at the Department of Radiology at Copenhagen University Hospital Hvidovre, with an
55
56 320 average dose-length product (DLP) of 225 mGy*cm, the effective dose of 2.9 mSv (data acquired
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58
59 321 from 41 shoulder scans performed January–November 2020) is comparable with approximately one
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4 322 year of background radiation in Denmark (3 mSv). The increased all-time risk of developing cancer
5
6 323 is estimated to 0.038% and 0.0618% for 20-year old male and female subjects at one examination,
7
8 324 with radiation levels obtained by the planned examination [31]. The variation in risk between the
9
10 325 sexes is mainly caused by radiation sensitivity of breast tissue in females.
11
12
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15 326 No severe safety issues are expected. However, there is always a risk of unknown side effects. In
16
17 327 this context, adverse events are defined as any unintended, unfavorable finding, symptom or disease
18
19 328 that occurs, whether it is related to the study or not. Adverse events are recorded. A critical adverse
20
21 329 event is defined as an event or reaction, which causes death, life-threatening situations,
22
23
24 330 hospitalization, or permanent or severe disability. Critical adverse events must be assessed by an
25
26 331 investigator to consider whether there is a reasonable possibility that it is caused by any procedure
27
28 332 related to the study. The following factors are included in the assessment: consistency in time,
29
30
31 333 consistency with the known effects of participation, and alternative causes. If a critical adverse
32
33 334 event is considered to have a causal relationship with the participation, the primary investigator, the
34
35 335 clinically responsible and the other investigators will evaluate whether the study should be
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37
38 336 terminated.
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41 337 **3.3 Education and training**
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43 338 The data collection is conducted by the primary investigator, or experienced staff appointed by the
44
45 339 primary investigator. Before commencing data collection, all involved staff is educated and trained
46
47 340 in the examination methods and questionnaires to be as calibrated as possible against each other.
48
49
50 341 There is a Standard Operating Procedures (SOP) file at all recruiting centers. In case a patient, from
51
52 342 questionnaires or when examined, shows signs or symptoms of affected mental or physical health
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54
55 343 the primary investigator is to be informed immediately, and appropriate measures carefully
56
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4 344 considered (termination of participation, treatment continuation, referral to general
5
6 345 practitioner/therapist/psychologist/psychiatrist).
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10 346 **3.4 Ethical considerations**
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12 347 All recruiting centers are specialized in treatment of patients with a wide variety of shoulder
13
14 348 pathologies, including traumatic instability. The study methods have been chosen specifically to
15
16 349 answer the research questions and for the objectives stated above. From the study results, we expect
17
18 350 to contribute to the understanding of the pathophysiology of traumatic anterior shoulder instability
19
20 351 and increase awareness of biomechanical and neuromuscular characteristics. We believe that the
21
22 352 potential benefits of using the chosen methods and enabling more efficient diagnostics, monitoring,
23
24 353 and treatment exceed the potential inconveniences of the study participants. The study is carried out
25
26 353 in accordance with the principles of the Helsinki Declaration and guidelines for Good Clinical
27
28 354 Practice (GCP).
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32
33 356 **3.5 Approvals**
35

36 357 The study was approved by the Capital Region Ethics Committee (journal-no: H-21027799) and the
37
38 358 Capital Region Knowledge Center for Data Reviews (journal-no: P-2021-842) before patient
39
40 359 recruitment began. The primary investigator is responsible of informing the Regional Committee on
41
42 360 Health Research Ethics of any critical adverse event and/or major changes of the protocol and files
43
44 361 all correspondences.
45
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48 49 362 **3.6 Data Management and Confidentiality**
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51 363 The study follows rules on data protection according to the Danish Data Protection Act throughout
52
53 364 the complete study period. The primary investigator, supervisors, and other assigned research staff
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55 365 have access to the dataset. The patients are identified by an assigned number. At the completion of
56
57 366 the study all identifiable data will be destroyed. The patients receive verbal and written information
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4 367 that data is stored and analyzed digitally, that the patient's anonymity is preserved, and that the data
5 protection legislation is adhered to.

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9 369 Data (demographics, clinical examinations, both PROM questionnaires and ultrasound
10 measurements) are managed using the software Research Electronic Data Capture (REDCap), a
11 370 web application for database management originally created at Vanderbilt University.
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16

17 372 **3.7 Dissemination**

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19 373 The results will be presented in three articles with the preliminary titles:
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- 21 374 1. *The effect of arthroscopic Bankart repair on shoulder biomechanics in patients with traumatic
22 anterior instability: A prospective cohort study*
23
24 375 2. *The effect of arthroscopic Bankart repair on neuromuscular control in patients with traumatic
25 anterior shoulder instability: A prospective cohort study*
26
27 376 3. *Clinical outcomes following arthroscopic Bankart repair in patients with traumatic anterior
28 shoulder instability: A prospective cohort study*
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31 377
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36
37
38 380 The study results will be published in international peer-reviewed journals, online and in other
39 relevant media, presented at medical conventions and disseminated to clinicians and patients as
40 appropriate. Authorship is given based on the Vancouver criteria.

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43 383 **4. Trial status**

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45 384 Patient recruitment began 1 April 2022 and is expected to last for 36 months.
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48
49 385 **5. Discussion**

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51 386 The shoulder joint is the most mobile of all human joints and consequently the most unstable. The
52 shoulder is in fact the most commonly dislocated joint in the body. The resulting shoulder
53 387 instability leads to pain, weakness, and loss of shoulder function, and can have life-lasting
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55 388 consequences. Understanding of the complete damage caused by shoulder dislocation is lacking and
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4 390 management of the condition is incomprehensive. There is evidence that biomechanics and
5
6 neuromuscular control change following shoulder dislocation, but it remains to be established if
7
8 measurements hereof are applicable in the clinical setting [8,9].
9
10

11 393 This study is, to our knowledge, the first with a multi-perspective approach focusing on
12
13 394 biomechanical and neuromuscular functions to assess the effect of arthroscopic Bankart repair in a
14
15 group of patients with traumatic shoulder instability. The study methods have been chosen
16 395 specifically to reach the objectives stated above and have been approved by the regional Ethics
17
18 396 Committee. As the literature on biomechanical and neuromuscular changes in patients with
19
20 397 traumatic shoulder instability is scarce, the authors cannot refer to any established standard
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22 398 deviations or minimally important difference. Hence, the study is essentially exploratory.
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27 400 Ultimately, the aim is to create grounds for evidence-based decision-making and development of
28
29 401 clinical guidelines. The authors believe the study results can contribute to changed management of
30
31 402 shoulder instability and optimized health system spending.
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35 403 **6. Data availability statement**
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37 404 No data are currently available for sharing.
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4 501 **Footnotes:**

5 502 Contributors: CM and KWB initiated the study. CM, KRA, BHK and JB planned the study and
6 developed the protocol. KWB and PH provided critical feedback about the protocol. Data
7 acquisition is performed by CM and KRA, who will also analyze the data. All authors have read
8 and contributed to the manuscript above, given approval, and agreed to be accountable for all
9 aspects of the work.

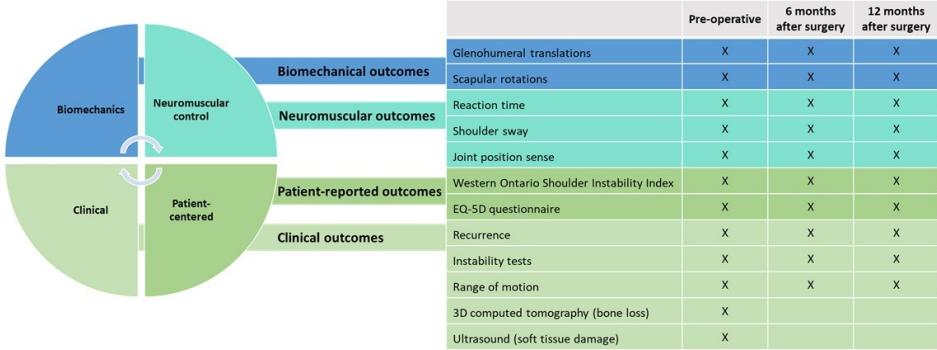
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11 504
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14 507 Funding: The project has received grants from the private fund “Familien Hede Nielsens Fond”
15 (grant number 2020-1172) and the Copenhagen University Hospital Amager & Hvidovre Research
16 Fund (grant number NA).

17
18 509
19 510 Competing interests: None declared.

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21 511 Provenance and peer review: Not commissioned; externally peer reviewed.

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4 512 **Figure legends:**
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7 513 **Figure 1.** The investigation approach with biomechanical, neuromuscular, patient-centered, and
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9 514 clinical outcomes.
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For peer review only



205x83mm (150 x 150 DPI)

Baseline Demographics

Form Status

Subject ID

Gender

- Male
- Female
- Other

Weight, kg w. 1 decimal

(Vægt i kg, med 1 decimal)

Height, cm

(Højde i cm)

BMI

(BMI: vægt/(højde*højde) kg og cm)

Dominant side

- right
- left
- both
- other

If other, explain

Injured shoulder, side

- Right
 - Left
- (Beskadiget skulder, side)
-

Primary injury mechanism

- Fell on outstretched arm
 - Fell directly on shoulder
 - Arm was pulled
 - External force to shoulder
 - Other
- (Skadesmekanisme)
-

If 5) other, explain:

(Hvis anden skadesmekanisme, da uddyb)

1 No. dislocations of injured shoulder

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No. dislocations of injured shoulder

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>20

Only subluxation(s)
(Antal luksationer)

Previous treatment(s) of shoulder instability

Home-based exercise

Supervised exercise (physiotherapy)

Passive treatment (manipulation, massage, acupuncture)

Chiropractor

Pain relievers

Other medicines

Other

Tidl. forsøgt behandling(er)

If either:
smertestillende medicin
anden medicinsk behandling
anden behandling,
explain:

(Uddyb medicinsk behandling/anden behandling)

Pre-injury activity level. (ADL: bathing, dressing, toileting, transferring (moving to and from a bed or a chair), eating, and continence).

Limited ADL

Unlimited ADL

Physical activity w. affected limb 1-3/w.

Physical activity w. affected limb >3/w.
(Fysisk aktivitet før skade)

Post-injury activity level. (ADL: bathing, dressing, toileting, transferring (moving to and from a bed or a chair), eating, and continence).

Limited ADL

Unlimited ADL

Physical activity w. affected limb 1-3/w.

Physical activity w. affected limb >3/w.
(Fysisk aktivitet efter skade)

For peer review only

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5 KLINISK SKULDERUNDERSØGELSE - Bankart
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Marker dominant side	HØ	VE
Inspektion		
Palpation		
Flexion		
Extension		
Abduktion		
IR		
ER		
Hawkins		
Empty can scaption +force		
Jobe's		
Adduction +thumbs up/down		
O'Brien's		
Sulcus test		
Load and shift		
Apprehension		
Relocation		

Denmark Danish Eq5d5l Redcap Self Complete Web

1 Venligst udfyld spørgeskema nedenunder.

2
3 Tak og mvh

4
5 Catarina Malmberg, læge og PhD-studerende

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8
9 Du bedes klikke med musen i DEN kasse, der bedst beskriver dit helbred I DAG.

10
11 BEVÆGELIGHED

- 12
13 Jeg har ingen problemer med at gå omkring
14 Jeg har lidt problemer med at gå omkring
15 Jeg har moderate problemer med at gå omkring
16 Jeg har store problemer med at gå omkring
17 Jeg kan ikke gå omkring

18
19 © EuroQol Research Foundation. EQ-5D™ is a trade mark of the EuroQol Research Foundation

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21 Du bedes klikke med musen i DEN kasse, der bedst beskriver dit helbred I DAG.

22
23 PERSONLIG PLEJE

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25 Jeg har ingen problemer med at vaske mig eller klæde mig på
26 Jeg har lidt problemer med at vaske mig eller klæde mig på
27 Jeg har moderate problemer med at vaske mig eller klæde mig på
28 Jeg har store problemer med at vaske mig eller klæde mig på
29 Jeg kan ikke vaske mig eller klæde mig på

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32 © EuroQol Research Foundation. EQ-5D™ is a trade mark of the EuroQol Research Foundation

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34 Du bedes klikke med musen i DEN kasse, der bedst beskriver dit helbred I DAG.

35
36 SÆDVANLIGE AKTIVITETER (fx. arbejde, studie, husarbejde, familie- eller fritidsaktiviteter)

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38 Jeg har ingen problemer med at udføre mine sædvanlige aktiviteter
39 Jeg har lidt problemer med at udføre mine sædvanlige aktiviteter
40 Jeg har moderate problemer med at udføre mine sædvanlige aktiviteter
41 Jeg har store problemer med at udføre mine sædvanlige aktiviteter
42 Jeg kan ikke udføre mine sædvanlige aktiviteter

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45 © EuroQol Research Foundation. EQ-5D™ is a trade mark of the EuroQol Research Foundation

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47 Du bedes klikke med musen i DEN kasse, der bedst beskriver dit helbred I DAG.

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49 SMERTER / UBEHAG

- 50
51 Jeg har ingen smerter eller ubehag
52 Jeg har lidt smerter eller ubehag
53 Jeg har moderate smerter eller ubehag
54 Jeg har stærke smerter eller ubehag
55 Jeg har ekstreme smerter eller ubehag

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60 Du bedes klikke med musen i DEN kasse, der bedst beskriver dit helbred I DAG.

1) ANGST / DEPRESSION

- 2)
- 3) Jeg er ikke ængstelig eller deprimeret
- 4) Jeg er lidt ængstelig eller deprimeret
- 5) Jeg er moderat ængstelig eller deprimeret
- 6) Jeg er meget ængstelig eller deprimeret
- 7) Jeg er ekstremt ængstelig eller deprimeret
- 8)

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10)

11) Vi vil gerne vide, hvor godt eller dårligt dit
12) helbred er I DAG.

13) Denne skala er nummereret fra 0 til 100.

14) 100 svarer til det bedste helbred, du kan forestille
15) dig.
16) 0 svarer til det dårligste helbred, du kan forestille
17) dig.
18) Klik med musen på det sted på skalaen, der viser,
19) hvordan dit helbred er I DAG.

0 -
Det dårligste
helbred, du kan
forestille dig



(Place a mark on the scale above)

100 - Det
bedste helbred,
du kan forestille
dig

20) © EuroQol Research Foundation. EQ-5D™ is a trade mark of the EuroQol Research Foundation

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Spørgeskema om skulderfunktion (WOSI)

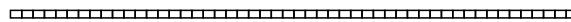
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2 Kære deltager
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4 Du bedes venligst at udfylde dette spørgeskema. Det er desværre ikke muligt at gemme undervejs, men hele
5 spørgeskemaet må besvares når du er startet (du kan til gengælg starte forfra, hvis du er nødt til at afbryde).
6

7 Tak for din deltagelse! Mvh projektansvarlige
8
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10
11 **Sektion A: De følgende spørgsmål drejer sig om de fysiske symptomer, du har på grund af dit**
12 **skulderproblem. Ved hvert spørgsmål skal du på linjen markere omfanget af dine symptomer**
13 **indenfor den seneste uge.**

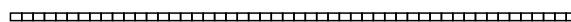
15 Hvor ondt gør det i din skulder, når du arbejder med
16 armen over hovedet?

Ingen smerte  Ekstrem smerte
(Place a mark on the scale above)

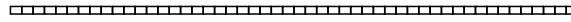
20 Hvor meget murren eller ømhed har du i skulderen?

Ingen Murren/
ømhed  Ekstrem
murren/ømhed
(Place a mark on the scale above)

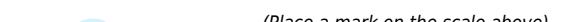
25 Hvor plaget er du af kraftnedsættelse eller manglende
26 styrke i din skulder?

Ingen
kraftnedsættelse  Ekstrem
kraftnedsættelse
(Place a mark on the scale above)

30 Hvor plaget er du af udtrætning eller manglende
31 udholdenhed i din skulder?

Ingen udtrætning  Ekstrem
udtrætning
(Place a mark on the scale above)

35 Hvor generet er du af klikken, knasen eller smæld i
36 skulderen?

Ingen klikken  Ekstrem klikken
(Place a mark on the scale above)

40 Hvor generet er du af stivhed i skulderen?

Ingen stivhed  Ekstrem stivhed
(Place a mark on the scale above)

45 Hvor meget ubehag har du i dine nakkemuskler som en
46 følge af dit skulderproblem?

Intet ubehag  Ekstremt ubehag
(Place a mark on the scale above)

50 Hvor ustabil eller løs er din skulder?

Ingen løshed  Ekstrem løshed
(Place a mark on the scale above)

55 Hvor meget kompenserer du for din skulder med brug af
56 andre muskler?

Slet ikke  Ekstremt
(Place a mark on the scale above)

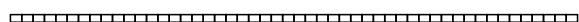
60 Hvor meget har du mistet af din bevægelighed i
skulderen?

Intet tab  Ekstremt tab
(Place a mark on the scale above)

1
2
3
4
**Sektion B: Følgende afsnit handler om, hvor meget dit skulderproblem har påvirket dit
arbejde, dine sports- og fritidsaktiviteter indenfor den seneste uge. Du skal igen til hvert
spørsmål markere omfanget af dine symptomer på linjen**

- 5
6 11) Hvor meget har dit skulderproblem begrænset dig i at Begrænset
7 deltagte i sport eller fritidsaktiviteter? ekstremt
8
9 (Place a mark on the scale above)
10
11 12) Hvor meget har skulderen indvirket på din evne til at Ekstrem
12 udføre specifikke færdigheder, som er nødvendige i indvirkning
13 din sport eller dit arbejde? (Hvis skulderen generer
14 både ved arbejde og sport skal du angive det i
15 forhold til der hvor den generer mest) Ingen indvirkning
16
17 (Place a mark on the scale above)
18
19 13) Hvor stort et behov har du for at beskytte din arm Ekstremt
20 under aktivitet? Slet ikke
21
22 (Place a mark on the scale above)
23
24 14) Hvor svært er det at løfte tunge ting under Ekstremt svært
25 skulderens niveau? Ikke svært
26
27 (Place a mark on the scale above)

1
2 **Sektion C: Følgende afsnit handler om, i hvor høj grad dit skulder problem har påvirket eller**
3 **ændret din livsstil. Du skal igen til hvert spørgsmål markere omfanget af dine symptomer på**
4 **linjen**

- 5) Hvor meget frygter du at falde på din skulder? Ingen frygt Ekstrem frygt
6) 
7) (Place a mark on the scale above)
8)
9)
10) I hvilken grad forhindrer dit skulderproblem dig i at holde dig i form? Slet ikke Ekstrem grad
11) 
12) (Place a mark on the scale above)
13)
14)
15) Hvor svært har du ved løssluppen aktivitet, så som brydning og slåskamp med familie og venner? Ingen besvær Ekstremt besvær
16) 
17) (Place a mark on the scale above)
18)
19)
20) Hvor meget søvnbesvær har du på grund af din skulder? Ingen besvær Ekstremt besvær
21) 
22) (Place a mark on the scale above)
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Sektion D: De følgende spørgsmål handler om, hvordan du har følt det den sidste uge med hensyn til dit skulderproblem. Marker omfanget på linjen

49) Hvor bevidst er du om din skulder?	Ikke bevidst	Ekstrem bevidst
		
	(Place a mark on the scale above)	
50) Hvor bekymret er du for at dit skulderproblem forværres?	Ikke bekymret	Ekstremt bekymret
		
	(Place a mark on the scale above)	
51) Hvor frustreret er du over din skulder?	Ikke frustreret	Ekstremt frustreret
		
	(Place a mark on the scale above)	

For peer review only

1 Biomechanical and Neuromuscular Characteristics in Patients with Traumatic Anterior Shoulder Instability Undergoing
2 Arthroscopic Bankart Repair: A Clinical Prospective Cohort Study Protocol
3

4 **1 General information**
5

6 **2 1. Place of investigation**
7

8 Sports Orthopedic Research Center – Copenhagen (SORC-C) and Human Movement Analysis
9
10 Laboratory, Department of Orthopedic Surgery, Copenhagen University Hospital Hvidovre,
11
12 Kettegård Allé 30, 2650 Hvidovre, Denmark
13
14

15 **2. Trial period**
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18 Anticipated: 1 April 2022 – 31 March 2026.
19
20

21 **3. Trial registration**
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24 The study protocol (Version 1.0) was published at Clinical Trials 27 April 2022
25
26 (www.clinicaltrials.gov, ID: NCT05250388) according to the World Health Organization Trial
27
28 Registration Data Set and follows the Standard Protocol Items: Recommendations for Interventional
29
30 Trials (SPIRIT) checklist. The study will adhere to the STROBE guidelines for reporting of cohort
31
32 studies (www.strobe-statement.org). The study has been approved by the Capital Region Ethics
33
34 Committee (journal-no: H-21027799) and the Capital Region Knowledge Center for Data Reviews
35
36 (journal-no: P-2021-842).
37
38

39 **4. Funding and insurance**
40
41

42 The study is a part of the PhD-project titled “Anterior-posterior glenohumeral translation in
43
44 traumatic anterior shoulder instability” funded partially by the Department of Orthopedic Surgery,
45
46 Copenhagen University Hospital Hvidovre (PhD-school, salary, overhead, lab costs). The PhD
47
48 project has received a grant from the private fund “Familien Hede Nielsens Fond” to cover
49
50 examination costs, whom did not have any involvement in study design; in the collection, analysis,
51
52 and interpretation of data; in the writing of the report; nor in the decision to submit the article for
53
54 publication. Further, the primary investigator has received a grant from the Copenhagen University
55
56
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4 Hospital Amager & Hvidovre research fund to cover salary. Further fundraising will continuously
5 be carried out through public and private foundations. There are no financial disclosures, from
6
7 private companies, research funds etc., within the research group that can compromise the integrity
8
9 of the project.
10
11
12

13
14 Study participants will not receive financial compensation. Study participants are covered by the
15 patient insurance of Copenhagen University Hospital Hvidovre.
16
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18

19
20 **30 5. Research group**
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22
23 *31 Primary investigator*
24

25 Catarina Malmberg (CM) is MD and PhD-student at the Department of Orthopedic Surgery,
26 Copenhagen University Hospital Hvidovre, and is the primary investigator, responsible for planning
27 and conducting the study in all its phases, as well as reporting to all relevant agencies. CM will be
28 first author of the paper on glenohumeral translation.
29
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35 Address: Sports Orthopedic Research Center – Copenhagen (SORC-C), Department of Orthopedic
36 Surgery, Copenhagen University Hospital Hvidovre, Kettegård Allé 30, 2650 Hvidovre, Denmark
37
38 Telephone: +4527519524, Email: catarina.anna.evelina.malmberg.02@regionh.dk
39
40
41

42
43 *39 Principal supervisor*
44

45 Kristoffer Weisskirchner Barfod is MD, PhD, and clinical associate professor at the Department of
46 Orthopedic Surgery, Copenhagen University Hospital Hvidovre. The principal supervisor of the
47 PhD follows requirements from the University of Copenhagen PhD-school throughout the PhD-
48 program. Barfod initiated the study together with CM and contributes to planning of the study and
49 review of the papers.
50
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3

4 45 *Co-supervisors*
5

6 46 Jesper Bencke is MSc, PhD, and biomechanical laboratory manager at the Department of
7 Orthopedic Surgery, Copenhagen University Hospital Hvidovre. Bencke contributes to planning of
8 the study and review of the papers. Bencke also consults the project with his knowledge in the
9 biomechanical and physiological field and supervise in the biomechanical laboratory.
10

11 49 Per Hölmich is DMSc, professor, and chief surgeon at the Arthroscopic Section, Department of
12 Orthopedic Surgery, Copenhagen University Hospital Hvidovre. Hölmich holds the responsibility
13 to secure that patients participating in the study are treated according to the highest medical
14 standard. Hölmich contributes to planning of the study and review of the papers.
15

16 50
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18 52
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26 54 *Collaborators*
27

28 55 Kristine Rask Andreasen, MD and PhD-student at the Department of Orthopedic Surgery,
29 Copenhagen University Hospital Hvidovre. Andreasen will assist in planning and managing the
30 neuromuscular tests, hereunder experimental work, clinical examinations, and data collection.
31

32 57 Andreasen will be first author of the paper on neuromuscular control.
33

34 58 Birgitte Hougs Kjær is MSc, PhD and Postdoc at the Department of Physical and Occupational
35 Therapy, Institute of Sports Medicine Copenhagen (ISMC), Copenhagen University Hospital
36 Bispebjerg & Frederiksberg. Hougs Kjær has specialized experience in musculoskeletal ultrasound
37 imaging and trained the primary investigator in performing the relevant examinations. Hougs Kjær
38 also contributes to planning of the study and review of the paper on glenohumeral translation.
39

40 64 Sanja Bay Hansen is MD at the Centre for Functional and Diagnostic Imaging and Research,
41 Dept. of Radiology, Hvidovre hospital. Hansen is responsible for quantifying bone loss from the
42 computed tomography (CT) scans according to state-of-the-art.
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1 Biomechanical and Neuromuscular Characteristics in Patients with Traumatic Anterior Shoulder Instability Undergoing
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3

4 67 Klaus Bak is MD and senior consultant at the Adeas hospital, Denmark. Bak is associate editor for
5 the medical journal Knee Surgery, Sports Traumatology, Arthroscopy (KSSTA). Bak contributes as
6 68 external assessor of the project.
7 69
8
9 70 *Recruiting centers*
10
11 71 Department of Orthopedic Surgery, Copenhagen University Hospital Amager & Hvidovre
12 72 Department of Orthopedic Surgery, Copenhagen University Hospital Herlev & Gentofte
13
14 73 Department of Orthopedic Surgery, Zealand University Hospital Køge
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16 74 Adeas Hospitals
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18 75 Gildhøj Private Hospital
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Information om forskningsprojektet 'Effekten af kikkertoperation på skulderstabiliteten hos patienter med instabilitet efter traume'

Du er blevet tilset af en ortopædkirurgisk læge, som har konstateret forreste skulderinstabilitet som skal behandles med kikkertoperation.



Vi ved at operation virker godt for langt de fleste, og vi vil med dette forskningsprojekt undersøge hvorfor resultaterne er gode hos mange, men mindre gode hos andre. Vi vil undersøge hvordan operationen påvirker dine ledbånd, dine refleksbuer og din muskulære styring af skulderen. Herved håber vi på sigt at kunne forbedre behandlingen af de patienter som ikke opnår optimale resultater efter operation.

Den projektansvarlige vil efter dette besøg kigge på dine data og kontakte dig via telefon, for at høre om du er interesseret i at høre nærmere om projektet. Hvis det er tilfældet vil vi invitere dig til en samtale, hvor vi gennemgår den skriftlige deltagerinformation og du kan tage endelig stilling til, om du vil være med i projektet.

Forskningsprojektet ændrer ikke på din behandling, men du vil blive indkaldt til 3 ekstra undersøgelser (før operationen, samt hhv. 6 og 12 måneder efter operationen) og du vil få foretaget en udvidet røntgenundersøgelse (3D CT-scanning) af dine skuldre før operationen.

Du kan læse nærmere om forskningsprojektet i den vedlagte deltagerinformation.

Hvis du spørgsmål er du velkommen til at kontakte mig via nedenstående mail eller telefonnummer.

Mvh

Catarina Malmberg, læge, PhD-studerende og projektansvarlige

Mail: catarina.anna.evelina.malmberg.02@regionh.dk

Telefonnummer: 2751 9524



En undersøgelse af effekten af kikkertkirurgi på skulderstabiliteten hos patienter med instabilitet efter traume

Vil du deltag i et videnskabeligt forsøg?

Vi vil spørge, om du vil deltag i et sundhedsvidenskabeligt forskningsprojekt, der udføres af Ortopædkirurgisk afdeling på Hvidovre Hospital. Overordnet ansvarlig for forsøget er læge og PhD-studerende Catarina Malmberg.

Før du beslutter, om du vil deltage i forsøget, skal du fuldt ud forstå, hvad forsøget går ud på, og hvorfor vi gennemfører forsøget. Vi vil derfor bede dig om at læse denne deltagerinformation grundigt.

Udover denne pjece, vil du have en samtale med en af projektets forskere om forsøget, hvor deltagerinformationen vil blive uddybet, og hvor du kan stille de spørgsmål, du har om forsøget. Du er velkommen til at have et familiemedlem, en ven eller en bekendt med til samtalen.

Hvis du beslutter dig for at deltage i forsøget, vil vi bede dig om at underskrive en samtykkeerklæring. Husk, at du har ret til betænkningstid, før du beslutter, om du vil underskrive samtykkeerklæringen.

Det er frivilligt at deltage i forsøget. Du kan når som helst og uden at give en grund trække dit samtykke tilbage uden videre konsekvenser.

Formålet med forsøget

Skulderen er det led i kroppen som hyppigst går af led. Skaden medfører en instabilitet i leddet, og hos mange medfører det nedsat funktion, kroniske smerter og forringet livskvalitet. Om de fortsatte problemer skyldes at ledbåndene rives over, at knoglen deformeres, at nervernes refleksbuer ændres, eller en kombination af ovenstående som medfører at af evnen til styre skulderen går tabt, vides endnu ikke.

Typisk vil første behandlingsvalg være fysioterapi og ved manglende effekt kikkertoperation med genskabelse af leddets stabiliserende strukturer. Med dette studie ønsker vi at undersøge operationens effekt, dels på den mekaniske stabilitet og dels på nervernes refleksbuer (den neuromuskulære kontrol), og afklare om disse faktorer kan forklare de symptomer patienter oplever. Vores håb er på sigt at kunne adskille dem, som kan forvente et godt resultat ved fysioterapi fra dem, som vil have gavn af tidlig kirurgisk behandling. Det ville medføre at man tidligt i forløbet vil kunne finde den behandling som fører til bedst mulige slutresultat, og derved bidrage til en mere effektiv og korrekt behandling af skulderinstabilitet.

Studiet udføres på Hvidovre Hospital, hvor alle kontroller vil finde sted. 55 patienter med traumatisk skulderinstabilitet og planlagt kikkertoperation vil blive inviteret til at deltage, med start fra 1. september 2021.

Forsøgets praktiske udførelse

Som deltager i projektet vil du skulle møde til 3 kontroller; før din operation, samt hhv. 6 og 12 måneder efter operationen. Det forventes at hvert besøg vil vare ca. 2 timer. Ved disse besøg skal du møde i Bevægelseslaboratoriet i Ortopædkirurgisk afdeling på Hvidovre hospital, hvor en fagkyndig person vil undersøge dine skuldre med en række forskellige stabilitets- og funktionstests.



Først vil vi lave en almindelig skulderundersøgelse, ligesom den Du tidligere har fået foretaget hos den kirurg som skal operere dig. Det indebærer, at vi vil bede dig om at bevæge armene i det omfang du kan, samt med vores hænder mærke efter om vi kan fremkalde den løshed og gener som du oplever.

Desuden vil vi ved de tre besøg udføre tests i laboratoriet, hvor vi med højteknologiske hjælpemidler analyserer dine skuldres bevægelsesmønster og din evne til at lokalisere arm og skulder i rummet. Disse inkluderer:

- En test hvor du får påklistret en række markører på og omkring din skulder og bliver bedt om at udføre nogle bestemte bevægelser, samtidig med du bliver filmet. Et antal kameraer i laboratoriet opsamler signaler fra markørerne, som føres videre til en computer, og som beregner og analyserer dit bevægelsesmønster.
- En undersøgelse hvor vi placerer din arm i to forskellige positioner, og med ultralyd kigger direkte ind i dit skulderled samtidig med at du er: i hvile, får et let tryk bagfra, eller drejer din arm enten indad eller udad.
- En test af stillingssans hvor du med lukkede øjne bliver bedt om at genfinde en tidligere position, hvor armen var løftet.
- En "svajetest" hvor du ligger i en plankeposition med underkroppen støttet af en briks og, hhv. med ansigtet nedad og til siden, støtter på skiftevis den ene og den anden arm i 30 sekunder.
- En test af reaktionstid, hvor du bærer et armbånd, der via en ledning over en trisse er forbundet til en elektromagnet med en lodret hængende vægt som trækker let i din arm. Pludselig deaktiveres magneten, og håndvægten slipper, hvilket vil få din skulder at bevæge sig i modsat retning. Den tid du bruger på at reagere, og føre hånden tilbage til udgangspositionen, er reaktionstiden.

Du vil desuden få tilsendt 2 elektroniske spørgeskemaer på mail, vedrørende din skulderfunktion- og smerter, som du vil blive bedt om at udfylde i forbindelse med de tre kontroller.

Inden operationen vil vi foretage en udvidet computerassisteret tomografi (3D CT-scanning) af begge dine skuldre for at vurdere størrelsen af et eventuel knogletab.

Vi vil sammen fastlægge en dato for næste kontrol fra gang til gang, under hensyn til, hvad der er hensigtsmæssigt for dig.

Medicin

Som deltager i projektet vil du ikke skulle tage nogen medicin, og det har ingen indflydelse på medicin som du eventuelt tager i forvejen.

Personlige og journaloplysninger

Ved at skrive under på det informerede samtykke gives forsøgsansvarlige, samt eventuel kontrolmyndighed direkte adgang til at indhente oplysninger i din journal mv., herunder elektronisk journal, med henblik på at se oplysninger om dine helbredsforhold, som er nødvendige som led i gennemførelsen af forskningsprojektet samt i kontroløjemed, herunder egenkontrol, kvalitetskontrol og monitorering, som disse er forpligtet til at udføre. Der henvises til komitelovens § 3, stk. 3 og anmeldelsesbekendtgørelsen § 4, stk. 1, samt § 10, stk. 3 og stk. 5.

De journaloplysninger der er relevante for os er:

1. Dine kontaktoplysninger, som vi anvender til at kontakte dig ud fra.
2. Informationer omhandlende behandling af din skulder, for at sikre at du opfylder kriterierne for deltagelse.
3. Dine billeddiagnostiske undersøgelser (røntgen, CT-scanning), som vi bruger til at undersøge et eventuelt knogletab.



Alle involverede forskere har tavshedspligt og vil behandle dine personlige data strengt fortroligt. Personlige oplysninger vil i gennem hele forsøgets forløb beskyttes ifølge den Danske Databeskyttelsesforordning og Databeskyttelsesloven. Det skal understreges at resultater udelukkende vil blive offentliggjort i anonymiseret form, og hverken navn, CPR- eller deltagernummer vil figurere andre steder end på et sikret, lukket drev. Hvis du vælger at trække dit informerede samtykke tilbage vil ingen nye data blive indsamlet og registreret. Imidlertid tillader lovgivningen, at data indsamlet inden du trækker dit samtykke tilbage stadig indgår i forsøgets datamateriale.

Forsøgets nytte

Som deltager i projektet vil du få en grundig opfølgning af fagpersoner specialiseret i din type skade. Derudover vil du med din deltagelse medvirke til at forbedre undersøgelse og behandling af skulderinstabilitet.

Bivirkninger, risici, og ulemper

Det er en ulempe for dig at skulle møde til de 3 kontroller. Til gengæld får du en grundig opfølgning af din skulder, som potentielt kan bidrage til, at du hurtigere genvinder din oprindelige funktion. Derudover vil din deltagelse i projektet ikke have indflydelse på din behandling.

Den røntgenundersøgelse som vil blive foretaget inden operationen medfører stråling, som potentielt kan øge livstidsrisikoen for kræft. Denne risiko er dog meget lille, og mængden af stråling kan sammenlignes med et års baggrundsstråling i Danmark.

De undersøgelsesmetoder som er inkluderede i projektet i øvrigt er ikke forbundet med kendte sundhedsskadelige risici, men der kan være risici ved forsøget, som vi endnu ikke kender. Under nogle af undersøgelerne vil din skulder være i positioner som kan fremkalde symptomer som smerter, usikkerhed og ubehag. De vil formentlig ligne de symptomer som du i forvejen oplever fra din skulder. Der vil i hele forløbet være en fagkyndig person til stede, med overblik over om undersøgelsen skal pauseres eller afbrydes. Vi beder dig derfor om at fortælle, hvis du oplever problemer med dit helbred, mens forsøget står på. Hvis vi opdager bivirkninger, som vi ikke allerede har fortalt dig om, vil du naturligvis blive orienteret med det samme, og du vil skulle tage stilling til, om du ønsker at fortsætte forsøget.

Udelukkelse fra/afbrydelse af forsøg

Vurderes det, at du ikke følger forsøgsplanen eller oplever bivirkninger som kan påvirke dit fysiske eller psykiske helbred kan du udelukkes fra videre deltagelse i forsøget. Opstår der alvorlige uventede bivirkninger vil forsøget blive afbrudt. Andre årsager til afbrydelse af studiet kan være mangel på deltagere, eller at sufficient datamængde foreligger.

Økonomiske forhold

Der udbetales IKKE vederlag for deltagelse i forsøget. I tilfælde af komplikationer, er deltageren dækket af Hvidovre Hospitals patientforsikring og arbejdsskadeforsikringsloven.

Læge og PhD-studerende Catarina Malmberg og overlæge og klinisk lektor Kristoffer W Barfod har taget initiativ til projektet. Faciliteter i form af undersøgelseslokaler og røntgen stilles til rådighed af Hvidovre Hospital, og projektet finansieres overordnet af Ortopædkirurgisk afdeling. Forsøget har modtaget 20 000 kr. i støtte fra Familien Hede Nielsens Fond. Der søges om yderligere finansiering fra private og offentlige fonde. Hvis yderligere støtte modtages, vil deltagere og Videnskabsetisk Komité blive kontaktet herom. De



involverede forskere har ingen økonomisk udbytte af studiet.

Adgang til forsøgsresultater

Resultaterne vil blive offentliggjort, og udgivet i et internationalt videnskabeligt tidsskrift. Yderligere vil resultaterne blive fremlagt på fagspecifikke kongresser.

Forsøget anses for afsluttet når 55 deltagere har gennemført forsøget. Dette forventes udført inden udgangen af september 2024.

Originaltitel

Forsøgets engelske originaltitel er: 'The effect of arthroscopic Bankart repair on anterior-posterior glenohumeral translation and shoulder proprioception in patients with traumatic anterior shoulder instability: a prospective cohort study'

Det er frivilligt at deltage i forsøget

Vi håber, at du med denne information har fået tilstrækkeligt indblik i, hvad det vil sige at deltage i forsøget, og at du føler dig rustet til at tage beslutningen om din eventuelle deltagelse. Vi beder dig også om at læse det vedlagte materiale "Forsøgspersonens rettigheder i et sundhedsvidenskabeligt forskningsprojekt".

Yderligere oplysninger om forsøget kan fås ved kontakt til projektansvarlig:

Læge, PhD-studerende Catarina Malmberg
Ortopædkirurgisk ambulatorium, afsnit 333, Hvidovre Hospital
Kettegård Allé 30, 2650 Hvidovre
Mail: catarina.anna.evelina.malmberg.02@regionh.dk
Telefon: 27519524 / 38623862

Forsøgspersoners rettigheder i et sundhedsvidenskabeligt forskningsprojekt

Som deltager i et sundhedsvidenskabeligt forskningsprojekt skal du vide, at:

- din deltagelse i forskningsprojektet er helt frivillig og kun kan ske efter, at du har fået både skriftlig og mundtlig information om forskningsprojektet og underskrevet samtykkeerklæringen.
- du til enhver tid mundtligt, skriftligt eller ved anden klar tilkendegivelse kan trække dit samtykke til deltagelse tilbage og udtræde af forskningsprojektet. Såfremt du trækker dit samtykke tilbage påvirker dette ikke din ret til nuværende eller fremtidig behandling eller andre rettigheder, som du måtte have.
- du har ret til at tage et familiemedlem, en ven eller en bekendt med til informationssamtalen.
- du har ret til betænkningstid, før du underskriver samtykkeerklæringen.
- oplysninger om dine helbredsforhold, øvrige rent private forhold og andre fortrolige oplysninger om dig, som fremkommer i forbindelse med forskningsprojektet, er omfattet af tavshedspligt.
- behandling af oplysninger om dig, herunder oplysninger i dine blodprøver og væv, sker efter reglerne i databeskyttelsesforordningen, databeskyttelsesloven samt sundhedsloven. Den dataansvarlige i forsøget skal orientere dig nærmere om dine rettigheder efter databeskyttelsesreglerne.
- der er mulighed for at få aktindsigt i forsøgsprotokoller efter offentlighedslovens bestemmelser. Det vil sige, at du kan få adgang til at se alle papirer vedrørende forsøgets tilrettelæggelse, bortset fra de dele, som indeholder forretningshemmeligheder eller fortrolige oplysninger om andre.
- der er mulighed for at klage og få erstatning efter reglerne i lov om klage- og erstatningsadgang inden for sundhedsvæsenet. Hvis der under forsøget skulle opstå en skade kan du henvende dig til Patienterstatningen, se nærmere på www.patienterstatningen.dk

De Videnskabsetiske Komiteer for Region Hovedstaden (6 komiteer)
Tlf.: +45 38 66 63 95
E-mail: vek@regionh.dk
Hjemmeside: www.regionh.dk/vek

Den Videnskabsetiske Komité for Region Sjælland
Tlf.: +45 93 56 60 00
E-mail: RVK-sjaelland@regionsjaelland.dk
Hjemmeside:
<https://www.regionsjaelland.dk/sundhed/forskning/forfagfolk/videnskabsetisk-komite/Sider/default.aspx>

De Videnskabsetiske Komiteer for Region Syddanmark (2 komiteer)
Tlf.: +45 76 63 82 21
E-mail: komite@rsyd.dk
Hjemmeside: www.regionssyddanmark.dk/komite

De Videnskabsetiske Komiteer for Region Midtjylland (2 komiteer)
Tlf.: +45 78 41 01 83 / +45 78 41 01 82 / +45 78 41 01 81
E-mail: komite@rm.dk
Hjemmeside: www.komite.rm.dk

Den Videnskabsetiske Komité for Region Nordjylland Tlf.: +45 97 64 84 40
E-mail: vek@rn.dk
Hjemmeside: www.rn.dk/vek

National Videnskabsetisk Komité
Tlf.: +45 72 21 68 55
E-mail: kontakt@nvk.dk
Hjemmeside: www.nvk.dk

Dette tillæg er udarbejdet af det videnskabsetiske komitésystem og kan vedhæftes den skriftlige information om det sundhedsvidenskabelige forskningsprojekt. Spørgsmål til et konkret projekt skal rettes til projektets forsøgsansvarlige. Generelle spørgsmål til forsøgspersoners rettigheder kan rettes til den komité, som har godkendt projektet.

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Hvidovre
Hospital

SORC-C
Sports Orthopedic Research Center - Copenhagen



Informeret samtykke til deltagelse i videnskabeligt forskningsprojekt

Forskningsprojektets titel:

Effekten af kikkertkirurgi på biomekanik og neuromuskulær kontrol hos patienter med forreste skulderinstabilitet efter traume: Et prospektivt cohortestudie

Erklæring fra forsøgspersonen:

Jeg har fået skriftlig og mundtlig information og jeg ved nok om formål, metode, fordele og ulemper til at sige ja til at deltage.

Jeg ved, at det er frivilligt at deltage, og at jeg altid kan trække mit samtykke tilbage uden videre konsekvenser.

Jeg giver samtykke til, at deltage i forskningsprojektet. Jeg har fået en kopi af dette samtykkeark samt en kopi af den skriftlige information om projektet til eget brug.

Forsøgspersonens navn: _____

Dato: _____ Underskrift: _____

Ønsker du at blive informeret om forskningsprojektets resultat samt eventuelle konsekvenser?:

Ja Nej

Ønsker du at blive informeret om væsentlige oplysninger om din egen helbredstilstand?:

Ja Nej

Erklæring fra den, der afgiver informationen:

Jeg erklærer, at forsøgspersonen har modtaget mundtlig og skriftlig information om forsøget og har haft mulighed for at stille spørgsmål.

Efter min overbevisning er der givet tilstrækkelig information til, at der kan træffes beslutning om deltagelse i forsøget.

Navnet på den, der har afgivet informationen: _____

Dato: _____ Underskrift: _____

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STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No.	Recommendation	Page No.	Relevant text from manuscript
Title and abstract	1	(a) Indicate the study's design with a commonly used term in the title or the abstract (b) Provide in the abstract an informative and balanced summary of what was done and what was found	Page 1 Page 2	Line #1-3 Line #17-39
Introduction				
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Page 4-5	Line #48-87
Objectives	3	State specific objectives, including any prespecified hypotheses	Page 6-7	Line #96-130
Methods				
Study design	4	Present key elements of study design early in the paper	Page 7	Line #132-135
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Page 11 Page 13	Line #213-221 Line #253-254, #262-264
Participants	6	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants (b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case	Page 11-12 N/A	Line #223-251 N/A
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Page 7-11	Line #137-211
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Page 7-11	Line #137-211
Bias	9	Describe any efforts to address potential sources of bias	Page 17	Line #338-345
Study size	10	Explain how the study size was arrived at	Page 14	Line #274-280

Continued on next page

1	Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Page 14-15 Line #279-291
2	Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding (b) Describe any methods used to examine subgroups and interactions (c) Explain how missing data were addressed (d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed <i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy (e) Describe any sensitivity analyses	Page 14-15 N/A Page 15-16 Line #272-297 N/A Page 15-16 Line #289-293 Line #289-293 N/A
3	Results			
4	Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram	N/A N/A N/A
5	Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)	N/A N/A N/A
6	Outcome data	15*	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time <i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure <i>Cross-sectional study</i> —Report numbers of outcome events or summary measures	N/A N/A N/A
7	Main results	16	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included (b) Report category boundaries when continuous variables were categorized (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A N/A N/A

Continued on next page

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1	Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	N/A	N/A
Discussion					
5	Key results	18	Summarise key results with reference to study objectives	N/A	N/A
6	Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	N/A	N/A
7	Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence		N/A
8	Generalisability	21	Discuss the generalisability (external validity) of the study results		N/A
Other information					
14	Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	pl. 1, Line #17-27	

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.