

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

General information

1. Place of investigation

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

2. Trial period

Anticipated: 1 April 2022 – 1 April 2025.

3. Trial registration

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

4. Funding and insurance

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

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

Hospital Amager & Hvidovre research fund to cover salary. Further fundraising will continuously be carried out through public and private foundations. There are no financial disclosures, from private companies, research funds etc., within the research group that can compromise the integrity of the project.

Study participants will not receive financial compensation. Study participants are covered by the patient insurance of Copenhagen University Hospital Hvidovre.

5. Research group

Primary investigator

Catarina Malmberg (CM) is MD and PhD-student at the Department of Orthopedic Surgery, Copenhagen University Hospital Hvidovre, and is the primary investigator, responsible for planning and conducting the study in all its phases, as well as reporting to all relevant agencies. CM will be first author of the paper on glenohumeral translation.

Address: Sports Orthopedic Research Center – Copenhagen (SORC-C), Department of Orthopedic Surgery, Copenhagen University Hospital Hvidovre, Kettegård Allé 30, 2650 Hvidovre, Denmark
Telephone: +4527519524, Email: catarina.anna.evelina.malmberg.02@regionh.dk

Principal supervisor

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

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

45 *Co-supervisors*

46 Jesper Bencke is MSc, PhD, and biomechanical laboratory manager at the Department of
47 Orthopedic Surgery, Copenhagen University Hospital Hvidovre. Bencke contributes to planning of
48 the study and review of the papers. Bencke also consults the project with his knowledge in the
49 biomechanical and physiological field and supervise in the biomechanical laboratory.
50 Per Hölmich is DMSc, professor, and chief surgeon at the Arthroscopic Section, Department of
51 Orthopedic Surgery, Copenhagen University Hospital Hvidovre. Hölmich holds the responsibility
52 to secure that patients participating in the study are treated according to the highest medical
53 standard. Hölmich contributes to planning of the study and review of the papers.

54 *Collaborators*

55 Kristine Rask Andreasen, MD and PhD-student at the Department of Orthopedic Surgery,
56 Copenhagen University Hospital Hvidovre. Andreasen will assist in planning and managing the
57 neuromuscular tests, hereunder experimental work, clinical examinations, and data collection.
58 Andreasen will be first author of the paper on neuromuscular control.
59 Birgitte Hougs Kjær is MSc, PhD and Postdoc at the Department of Physical and Occupational
60 Therapy, Institute of Sports Medicine Copenhagen (ISMC), Copenhagen University Hospital
61 Bispebjerg & Frederiksberg. Hougs Kjær has specialized experience in musculoskeletal ultrasound
62 imaging and trained the primary investigator in performing the relevant examinations. Hougs Kjær
63 also contributes to planning of the study and review of the paper on glenohumeral translation.
64 Sanja Bay Hansen is MD at the Centre for Functional and Diagnostic Imaging and Research,
65 Dept. of Radiology, Hvidovre hospital. Hansen is responsible for quantifying bone loss from the
66 computed tomography (CT) scans according to state-of-the-art.

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

67 Klaus Bak is MD and senior consultant at the Adeas hospital, Denmark. Bak is associate editor for
68 the medical journal Knee Surgery, Sports Traumatology, Arthroscopy (KSSTA). Bak contributes as
69 external assessor of the project.

70 *Recruiting centers*

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

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

73 Department of Orthopedic Surgery, Zealand University Hospital Køge

74 Adeas Hospitals

75 Gildhøj Private Hospital