HIT-AAA: Study Data Collection Form (Case Report Form)

Participant study number: _____ Participant initials: _____

Site: South Tees / York / Sheffield

Paperwork checklist (please tick):

- Written informed consent provided? [ ]
- Patient information sheet and copy of consent to patient [ ]
- Patient information sheet and copy of consent in medical notes [ ]
- Place study sticker in patient's notes [ ]
- Complete GP letters informing of patient's entry into study [ ]

1. Baseline data (week 0) **Date……**

Age	years	**Body mass**	kg
Sex		**Stature**	cm
Body mass index	kg/m^2	**Size of AAA**	cm
Baseline observations	BP:	RHR:	Sats: %
Date of vascular pre-assessment clinic			
METs score			
ASA score			
Modified revised cardiac risk index (answer yes or no)			
	Ischaemic heart disease		
	Congestive cardiac failure		
	Cerebrovascular disease		
	Insulin for diabetes mellitus		
	Creatinine > 177 µmol/l		
	Age >70 years		
	Abnormal electrocardiogram		
	Rhythm (other than sinus)		
Quantify abnormality			
	Uncontrolled blood pressure (systolic >160 mmHg, diastolic >90 mmHg)		
Other co-morbidities	Chronic obstructive pulmonary disease		
	Asthma		
	Other respiratory disease		
	Smoker (also tick if quit within 6 months)		
	Diabetes mellitus		
	Peripheral arterial disease		
	Gastrointestinal disease		
	Other (free text):		
Baseline creatinine (µmol/l)			
Baseline eGFR (ml/min)			
Baseline haemoglobin (mg/dL)			
Medications (please circle)	ACE inhibitor	Statin	Beta-blocker
	Calcium channel blocker	Antiplatelet A C D	Angiotensin II receptor antagonist
	NSAIDs	Diuretic	Insulin
	Warfarin	Oral hypoglycaemics	

A, aspirin; AAA, abdominal aortic aneurysm; ACE, angiotensin converting enzyme; ASA, American Society of Anesthesiologists; BP, blood pressure; C, clopidogrel; D, dypiridamole; eGMR, estimated glomerular filtration rate; MET, metabolic equivalents; NSAID, non-steroidal anti-inflammatory drug; RHR, resting heart rate.

Preference for exercise group (before randomisation) Yes / No

2. Baseline cardiopulmonary exercise test data (week 0)

Date……

Data	**Results or comment**	
Body mass		kg
Resting blood pressure		mmHg
Resting heart rate		beats/min
VO_2 at rest : Indexed		ml/kg/min
Absolute		ml/min
Anaerobic Indexed		ml/kg/min
threshold Absolute		ml/min
Power output at anaerobic threshold		W
Anaerobic threshold achieved (please circle)	Yes	No
VE/VCO_2 at anaerobic threshold		
VO_2 peak Indexed		ml/kg/min
Absolute		ml/min
Power output at VO_2 peak		W
O_2 pulse at the start of exercise		ml/beat
Peak O_2 pulse		ml/beat
Peak heart rate		beats/min
Peak blood pressure		mmHg
VE at rest		l/min
Peak VE		l/min
Inducible ischaemia (please circle)	Yes	No
Heart rate at ischaemia onset		beats/min
Ischaemia before / after anaerobic threshold (please circle)	Before	After
Oscillatory breathing pattern? (please circle)	Yes	No
Lowest exercise O_2 saturation		%
Oxygen Uptake Efficiency Slope (VO_2 ml/min / log VE l/min)		
Peak rating of perceived exertion		
Peak respiratory exchange ratio		
Reason for termination		

VCO_2, carbon dioxide production; VE, volume of expired air; VO_2, oxygen consumption.

3. Multi-disciplinary team data

Date…….

Type of surgery:	Open	EVAR	
Complexity of EVAR:	Complex	Non-complex	
Post-op destination:	Ward	HDU	ITU
Dated for surgery?	Yes	No	

Date if known: _____

4. Week 5 cardiopulmonary exercise test data

Date……

Data	**Results or comment**	
Body mass Resting blood pressure Resting heart rate		kg mmHg beats/min
VO_2 at rest : Indexed Absolute		ml/kg/min ml/min
Anaerobic threshold Indexed Absolute		ml/kg/min ml/min
Power output at anaerobic threshold		W
Anaerobic threshold achieved (please circle)	Yes	No
VE/VCO_2 at anaerobic threshold		
VO_2 peak Indexed Absolute		ml/kg/min ml/min
Power output at VO_2 peak		W
O_2 pulse at the start of exercise		ml/beat
Peak O_2 pulse		ml/beat
Peak heart rate Peak blood pressure		beats/min mmHg
VE at rest		l/min
Peak VE		l/min
Inducible ischaemia (please circle)	Yes	No
Heart rate at ischaemia onset		beats/min
Ischaemia before / after anaerobic threshold (please circle)	Before	After
Oscillatory breathing pattern? (please circle)	Yes	No
Lowest exercise O_2 saturation		%
Oxygen Uptake Efficiency Slope (VO_2 ml/min / log VE l/min)		
Peak rating of perceived exertion		
Peak respiratory exchange ratio		
Reason for termination		

VCO_2, carbon dioxide production; VE, volume of expired air; VO_2, oxygen consumption.

Preference for exercise group (following intervention) Yes / No

Week 5 Size of AAA (exercise group only) cm

If surgery delayed by >4 weeks please complete repeat exercise test sheet (p. 9)

5. Intra-operative data

Date of admission: _____

Date of intervention: _____

Days since last exercise test: _____ Test number: **1** **2** **3**

Intra-operative details

Type of repair (circle)	Open repair	EVAR
Open repair only:		
Surgical data	Aortic cross-clamp time	min
	Use of supra-renal clamp (please circle)	Yes / No min
Incision type (please circle)	Vertical / Transverse	
Other information (please circle)	Hostile abdomen Bi-iliac graft Inflammatory aneurysm	
Anaesthetic data for open repair or EVAR		
Type of anaesthetic Tick or comment as appropriate	General anaesthetic	
	Spinal	
	Spinal catheter	
	Epidural	Lumbar/Thoracic Intraop/ postop
	Combined spinal epidural anaesthesia	
	Local anaesthesia alone	
Estimated blood loss		ml
Urine output		ml
Intra-operative fluids	Crystalloids	ml
	Colloids	ml
	Cell salvaged blood	ml
	Packed cells	Units
	Fresh frozen plasma	Units
	Platelets	pools
	Cryoprecipitate	Units
Any intraoperative CVS support (circle)	Bolus	Infusion
Any intraoperative vasodilators (circle)	Bolus	Infusion
Requirement for CVS support at end of operation	Yes / No	Comment:
Post-operative care facility (circle)	Ward / HDU / ITU	

CVS, cardiovascular system; EVAR, endovascular aneurysm repair; HDU, high-dependency unit; ITU, intensive treatment unit.

Any intraoperative adverse events:

_____
_____
_____

Any adverse events between operation and midnight on day 0:

_____
_____
_____

Any other comments:

_____
_____
_____

Signature of intraoperative data collector: _____

6. Postoperative Morbidity (free text below) – including date

(a) Cardiac event

(b) Respiratory event

(c) Other event

Post-operative Morbidity Survey (POMS) data to be collected from end of surgery until discharge from hospital

7. Discharge Data

Date of discharge: _____

Date of death (write NA if not applicable): _____

Cause of death (write NA if not applicable): _____

Total hospital length of stay (nearest half day): _____

Days on ITU (write NA if not applicable): _____

Days on HDU (write NA if not applicable): _____

Date when POMS = 0: _____

8. Additional cardiopulmonary exercise test data

Date……

Data	**Results or comment**	
Body mass		kg
Resting blood pressure		mmHg
Resting heart rate		beats/min
VO_2 at rest : Indexed		ml/kg/min
Absolute		ml/min
Anaerobic threshold Indexed		ml/kg/min
Absolute		ml/min
Power output at anaerobic threshold		W
Anaerobic threshold achieved (please circle)	Yes	No
VE/VCO_2 at anaerobic threshold		
VO_2 peak Indexed		ml/kg/min
Absolute		ml/min
Power output at VO_2 peak		W
O_2 pulse at the start of exercise		ml/beat
Peak O_2 pulse		ml/beat
Peak heart rate		beats/min
Peak blood pressure		mmHg
VE at rest		l/min
Peak VE		l/min
Inducible ischaemia (please circle)	Yes	No
Heart rate at ischaemia onset		beats/min
Ischaemia before / after anaerobic threshold (please circle)	Before	After
Oscillatory breathing pattern? (please circle)	Yes	No
Lowest exercise O_2 saturation		%
Oxygen Uptake Efficiency Slope (VO_2 ml/min / log VE l/min)		
Peak rating of perceived exertion		
Peak respiratory exchange ratio		
Reason for termination		

VCO_2, carbon dioxide production; VE, volume of expired air; VO_2, oxygen consumption.

Postop day (0 = day of operation) **Days run from 0000 – 2359**	**1**	**2**	**3**	**4**	**5**	**6**	**7**
Put a tick in the box for each system if any criteria are fulfilled. **Level of care (1 / 2 / 3)** *All criteria are changes in comparison with preoperative status.*							
Pulmonary: New requirement for supplemental oxygen or other respiratory support. *(Include even if institutional practise or preventative for initial postoperative period)*							
Infectious: Currently on antibiotics or temperature >38 °C in the last 24 hr. *(Include antibiotic prophylaxis)*							
Renal: Presence of oliguria (500 ml/24 hr), OR increased serum creatinine (>30% from pre-op level) [baseline Cr x 1.3 = _____ µmol/L] OR urinary catheter in place.							
Gastro-intestinal: Unable to tolerate an enteral diet for any reason, including nausea, vomiting, and abdominal distension, or use of antiemetic.							
Cardiovascular system: Diagnostic tests or therapy within the last 24 h for any of the following: New myocardial infarction or ischaemia, Hypotension (requiring pharmacological therapy or fluid therapy >200 ml/hr), Atrial or ventricular arrhythmias, Cardiogenic pulmonary oedema, Thrombotic event (requiring anticoagulation).							
Central nervous system: Presence of new focal deficit, confusion, delirium or coma.							
Wound: Wound dehiscence requiring surgical exploration or drainage of pus from the operation wound.							
Haematological: Requirement for any of the following within the last 24 hr: packed erythrocytes, platelets, fresh-frozen plasma, or cryoprecipitate.							
Pain: New postoperative pain significant enough to require strong opioids or regional analgesia. (*score until epidural is removed, strong opioids are IV morphine or oxycodone/oxycontin)*							
Data collector initials							

Please provide comments overleaf detailing:

- Any significant morbidity not described above.
- Reasons why patient still in hospital if no morbidity described above.

If patient discharged, please complete discharge data on page eight of this form

Day	Post-operative comments (include initials of data collector)
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