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A randomised controlled trial of median Sternotomy versus anterolateral left Thoracotomy on morbidity and healthcare resource use in patients having off-pump coronary artery bypass surgery

Submission date 14/12/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 09/02/2007	**Overall study status** Completed	
Last Edited 03/07/2014	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CS2005/2169

Study information

Scientific Title

Acronym
SteT

Study objectives
The primary hypothesis is that off-pump coronary artery bypass thoracotomy (OPCAB-Th) will reduce post-operative morbidity and the amount of hospital resources used compared to off-pump coronary artery bypass sternotomy (OPCAB-St).

Ethics approval required
Old ethics approval format

Ethics approval(s)
NHS Southmead Research Ethics Committee, 11/08/2006, ref: 06/Q2002/53

Study design
Multi-centre open randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Coronary artery disease

Interventions

Coronary artery bypass grafting on the beating heart via a conventional median sternotomy (OPCAB-St) versus coronary artery bypass grafting on the beating heart via a left anterolateral thoracotomy (OPCAB-Th).

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
The primary outcome is the time until patients are classified as fit for discharge. A patient must have a chest X-ray with no evidence of pleural effusion requiring drainage, lung collapse /consolidation or pneumothorax, no suspected infection, normal routine blood tests and temperature in order to be classified as fit for discharge. Susceptibility to bias of these components of the primary outcome will be minimised by documenting objective clinical signs and measurements.

Secondary outcome measures
1. Intraoperative measurement of cardiac output measured by Swan-Ganz catheter, when each distal anastomosis is being carried out on the target coronary arteries (consecutive sub-sample only, n = 40)
2. A participants judgement about his or her readiness for discharge when the above criteria are met (too soon, about right, could have been discharged earlier)
3. Biochemical inflammatory markers, i.e. complement activation (C3a and C5), interleukin (Interleukin 6 [IL6], Interleukin 8 [IL8] and Interleukin 10 [IL10]); these will be assessed at five time points, i.e. preoperatively, at the end of the operation, and 4, 12 and 24 hours post-operatively (consecutive sub-sample only, n = 60)
4. Alveolar/arterial gradient measured preoperatively (in the anaesthetic room), after extubation, and 1 day after extubation, from arterial blood samples taken through an existing arterial line 5 minutes after administering oxygen by mask, for each of three different oxygen concentrations (consecutive sub-sample only, n = 40)
5. Pulmonary function tests (PFTs) preoperatively and at discharge
6. Pain score measured with a 10 cm (0 to 100 mm) visual analogue scale, or by verbal response (0 to 100) if a participant is not well enough to use the visual analogue scale at 2, 12, 24 and 36 hours after extubation and on discharge
7. The total amount (volume and dose) of local anaesthetic (paravertebral block) and patient-controlled analgesia administered; post-operative days on which paracetamol and non-steroidal anti-inflammatory drugs were dispensed
8. Intensive Care Unit (ICU) and post-operative hospital stay
9. In-hospital mortality and other standard measures of morbidity, e.g. post-operative myocardial infarction (MI), stroke, arrhythmia, need for haemodynamic support, renal failure and wound infection
10. Use of healthcare resources and associated costs, e.g. duration of operation, ICU/High Dependancy Unit (HDU) and ward stay, additional interventions to treat complications, readmissions
11. Coronary Revascularisation Outcome Questionnaire (CROQ) preoperatively (preoperative version) and at 3 months (postoperative version)

Overall study start date

08/01/2007

Completion date
31/12/2008

Eligibility

Key inclusion criteria
All adults aged more than 16 years and less than 80 years having non-emergency, scheduled (urgent or elective) first-time off-pump surgery represent the target study population.

Specific inclusion criteria:
1. Aged more than 16 and less than 80 years
2. Undergoing non-emergency, scheduled (urgent or elective) isolated coronary artery bypass grafting off-pump on the beating heart
3. Participating surgeon willing to carry out the operation via either surgical method

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
180

Key exclusion criteria
1. No previous cardiac surgery
2. No previous lung surgery
3. Not in another invasive research study

Date of first enrolment
08/01/2007

Date of final enrolment
31/12/2008

Locations

Countries of recruitment
England

Italy

Trinidad and Tobago

United Kingdom

Study participating centre
Bristol Heart Institute
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Sponsor information

Organisation
United Bristol NHS Healthcare Trust (UK)

Sponsor details
UBHT Research and Effectiveness Department
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Sponsor type
Hospital/treatment centre

Website
http://www.ubht.nhs.uk

ROR
https://ror.org/04nm1cv11

Funder(s)

Funder type
Charity

Funder Name
Garfield Weston Trust (UK) (ref: 06-07/1001)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/08/2013		Yes	No