

# 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

<b>Submission date</b> 14/12/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 09/02/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 03/07/2014	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

**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 Dependency 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**  
Bristol  
United Kingdom  
BS2 8HW

## **Sponsor information**

**Organisation**  
United Bristol NHS Healthcare Trust (UK)

**Sponsor details**  
UBHT Research and Effectiveness Department  
Bristol Royal Infirmary  
Marlborough Street  
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United Kingdom  
BS2 8HW

**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?
<a href="#">Results article</a>	results	01/08/2013		Yes	No