

Shortening cardioplegic arrest time during combined coronary and valvular surgery

Submission date 20/04/2007	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 13/06/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 27/04/2017	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Raimondo Ascione

Contact details
Bristol Heart Institute
University of Bristol
Level 7, Bristol Royal Infirmary
Marlborough Street
Bristol
United Kingdom
BS2 8HW
+44 (0)117 928 3145
r.ascione@bristol.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CS/2006/2267 (Sponsor's reference number)

Study information

Scientific Title

Shortening Cardioplegic Arrest Time during combined coronary and valvular surgery

Acronym

SCAT

Study objectives

Our primary hypothesis is that by modifying the way in which combined coronary artery bypass grafting (CABG) and valve replacement surgery is carried out cardioplegic arrest time can be shortened, reperfusion injury will be reduced and functional and clinical outcome improved compared to using the conventional method of surgery.

Conventionally the heart is arrested throughout both the valvular and coronary phases of the procedure using cold blood cardioplegia. With the modified hybrid approach the coronary surgery is carried out first on the beating heart with cardiopulmonary bypass, but without cardioplegic arrest. The heart is then arrested and the valve replacement surgery is carried out in the usual way.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NHS Southmead Research Ethics Committee, 21/06/2006, ref: 06/Q2002/52

Study design

Parallel-group randomised controlled trial with equal allocation

Primary study design

Interventional

Secondary study design

Randomised parallel trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Coronary artery and valve disease

Interventions

Patients will be prepared for surgery and anaesthetised according to standard protocols. Moderate hypothermic cardiopulmonary bypass (CPB) (32°C) will be used in all patients.

For the hybrid group, following establishment of CPB, left ventricular venting will be conventionally achieved through the right superior pulmonary vein. CPB mean arterial pressure will be maintained at 75 mmHg to optimise myocardial perfusion of the empty beating heart during coronary surgery. Coronary grafting will be according to our reported method for beating heart coronary surgery.

For both groups cardioplegic arrest will be achieved with cold (4 - 6°C) intermittent antegrade and retrograde blood cardioplegia. In the conventional surgery group the heart will be arrested throughout the operation. For the hybrid group cardioplegic arrest will be instituted after completion of the coronary surgery.

Intervention Type

Procedure/Surgery

Primary outcome measure

Composite endpoint of death, postoperative myocardial infarction, arrhythmia, requirement for pacing for more than 12 hours and/or inotropic support for more than 12 hours.

Secondary outcome measures

1. Clinical measures:

1.1. Duration of cardiopulmonary bypass

1.2. Duration of aortic cross clamp

1.3. Low cardiac output (LCO)

1.4. Blood loss

1.5. Transfusion requirement

1.6. Intubation time

1.7. Chest or wound infection

1.8. Any subsystem organ complication

1.9. Intensive Care Unit (ICU) and hospital stay

2. Metabolic stress: metabolites extracted from myocardial biopsies from the apex of the left ventricle will include adenine nucleotides and related compounds as well as amino acids (alanine /glutamate ratio) and lactate

3. Reperfusion injury: serum concentrations of troponin I will be determined prior to surgery, and at 1, 4, 12, 24, 48 and 72 hours post-operatively

Overall study start date

01/10/2007

Completion date

01/10/2010

Eligibility

Key inclusion criteria

1. Adults with multiple vessel coronary disease and any aortic valve disease and/or any mitral valve disease
2. Surgeons willing to carry out operation via either method

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

160

Key exclusion criteria

1. Single vessel coronary disease
2. Marked calcific degeneration of the mitral annulus
3. Reoperation
4. Malignancy
5. Debilitating neurological disease
6. Ongoing sepsis or endocarditis
7. Carotid artery stenosis greater than 75%
8. Critical limb ischaemia
9. Emergency operation for unstable angina
10. Salvage procedures

Date of first enrolment

01/10/2007

Date of final enrolment

01/10/2010

Locations**Countries of recruitment**

England

India

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
Bristol
England
United Kingdom
BS2 8HW
+44 (0)117 928 3473
debbie.mcphee@ubht.nhs.uk

Sponsor type

Hospital/treatment centre

Website

<http://www.ubht.nhs.uk>

ROR

<https://ror.org/04nm1cv11>

Funder(s)**Funder type**

Government

Funder Name

National Institute for Health Research (NIHR) (UK) - Biomedical Research Centre Programme

Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

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	01/08/2017		Yes	No