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Shortening cardioplegic arrest time during combined coronary and valvular surgery

Submission date	Recruitment status	[X] Prospectively registered
20/04/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
13/06/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
27/04/2017	Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Primary study design
Interventional

Study design
Parallel-group randomised controlled trial with equal allocation

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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
United Kingdom

England

India

Study participating centre
Bristol Heart Institute
Bristol
United Kingdom
BS2 8HW

Sponsor information

Organisation
United Bristol NHS Healthcare Trust (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

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