

# Shortening cardioplegic arrest time during combined coronary and valvular surgery

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<b>Registration date</b> 13/06/2007	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 27/04/2017	<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

**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

**Study design**

Parallel-group randomised controlled trial with equal allocation

**Primary study design**

Interventional

**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

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## 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?
<a href="#">Results article</a>	results	01/08/2017		Yes	No