

# A randomised trial of on pump beating heart surgery and blood cardioplegia in patients with impaired left ventricular function using cardiac magnetic resonance imaging and biochemical markers

|                                        |                                                   |                                                                                                   |
|----------------------------------------|---------------------------------------------------|---------------------------------------------------------------------------------------------------|
| <b>Submission date</b><br>24/10/2005   | <b>Recruitment status</b><br>No longer recruiting | <input type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol            |
| <b>Registration date</b><br>03/02/2006 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>04/07/2011       | <b>Condition category</b><br>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**  
COREC 05/Q1603/42

# Study information

## Scientific Title

## Study objectives

Beating heart surgery in patients with poor ventricular function leads to improved early end systolic volume index as measured by cardiac magnetic resonance imaging (MRI).

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethics approval received from Central Office for Research Ethics Committees (COREC) (ref: 05/Q1603/42)

## Primary study design

Interventional

## Study design

Randomised controlled trial

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Ischaemic heart disease

## Interventions

The trial involves comparing standard on pump warm blood cardioplegia coronary artery bypass grafting to a modified surgical technique where the patient undergoes beating heart surgery but is maintained on cardiopulmonary bypass to decompress the left ventricle.

## Intervention Type

Other

## Phase

Not Specified

## Primary outcome(s)

1. End systolic volume index
2. End diastolic volume index

## Key secondary outcome(s)

1. Hospital stay
2. Mortality
3. Creatine kinase myocardial bands (CKMB)
4. Troponin
5. Ventilation
6. Dialysis

- 7. Intra-aortic balloon pump (IABP) duration
- 8. Peak creatinine

**Completion date**

01/11/2007

## Eligibility

**Key inclusion criteria**

- 1. Ejection fraction less than 30%
- 2. Creatinine less than 170 µmol/l

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

- 1. Contra-indications to MRI scanning
- 2. Claustrophobia

**Date of first enrolment**

01/11/2005

**Date of final enrolment**

01/11/2007

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

Department of Cardiothoracic Surgery

Oxford

United Kingdom

OX3 9DU

# Sponsor information

## Organisation

Oxford Radcliffe Hospitals NHS Trust (UK)

## ROR

<https://ror.org/03h2bh287>

# Funder(s)

## Funder type

Charity

## Funder Name

British Heart Foundation (BHF) (UK) (ref: PG/05/037)

## Alternative Name(s)

The British Heart Foundation, the\_bhf, BHF

## Funding Body Type

Private sector organisation

## Funding Body Subtype

Trusts, charities, foundations (both public and private)

## 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 | 18/11/2008   |            | Yes            | No              |
| <a href="#">Results article</a> | results | 01/05/2011   |            | Yes            | No              |