

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

Submission date 24/10/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 03/02/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 04/07/2011	Condition category Circulatory System	<input type="checkbox"/> Individual participant data

Plain English Summary

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof David Taggart

Contact details

Department of Cardiothoracic Surgery
John Radcliffe Hospital
Headington
Oxford
United Kingdom
OX3 9DU
+44 (0)1856 221121
david.taggart@orh.nhs.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

COREC 05/Q1603/42

Study information

Scientific Title

Study hypothesis

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)

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Condition

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 measure

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

Secondary outcome measures

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

Overall study start date

01/11/2005

Overall study end date

01/11/2007

Eligibility

Participant inclusion criteria

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

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

50

Participant exclusion criteria

1. Contra-indications to MRI scanning
2. Claustrophobia

Recruitment start date

01/11/2005

Recruitment end date

01/11/2007

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Department of Cardiothoracic Surgery

Oxford

United Kingdom

OX3 9DU

Sponsor information

Organisation

Oxford Radcliffe Hospitals NHS Trust (UK)

Sponsor details

Ian Goodall

Research and Development Office

Oxford Radcliffe Hospitals NHS Trust

John Radcliffe Hospital

Headington

Oxford

England

United Kingdom

OX3 9DZ

+44 (0)1865 222757

ian.goodall@orh.nhs.uk

Sponsor type

Hospital/treatment centre

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_bhf, The British Heart Foundation, BHF

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

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	18/11/2008		Yes	No
Results article	results	01/05/2011		Yes	No