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	Recruitment status No longer recruiting	Prospectively registered		
24/10/2005		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
03/02/2006	Completed	[X] Results		
Last Edited 04/07/2011	Condition category Circulatory System	[] Individual participant data		

Plain English summary of protocol

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 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)

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

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 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

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

Age group

Adult

Sex

Both

Target number of participants

50

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

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 Radciffe 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