ISRCTN41388968 https://doi.org/10.1186/ISRCTN41388968

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

Registration date
03/02/2006

Overall study status
Completed

Last Edited
04/07/2011

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

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
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OX3 9DU

Sponsor information

Organisation
Oxford Radcliffe Hospitals NHS Trust (UK)

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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