Effects of off pump versus on pump coronary surgery on reversible and irreversible myocardial injury: a randomised trial using cardiovascular magnetic resonance imaging and biochemical markers

Submission date	Recruitment status No longer recruiting	Prospectively registered	
22/07/2005		[] Protocol	
Registration date	Overall study status	[] Statistical analysis plan	
22/07/2005	Completed	[X] Results	
Last Edited 12/06/2015	Condition category Circulatory System	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 066216

Study information

Scientific Title

Effects of off pump versus on pump coronary surgery on reversible and irreversible myocardial injury: a randomised trial using cardiovascular magnetic resonance imaging and biochemical markers

Study objectives

Using Cardiovascular Magnetic Resonance imaging (CMR), we compared the extent of perioperative myocardial reversible injury (myocardial stunning) and irreversible injury (myocardial necrosis) in patients undergoing multi-vessel Coronary Artery Bypass Graft surgery (CABG) with and without cardiopulmonary bypass, in a single center randomised trial.

To our knowledge, this is the first such study using cine and contrast-enhanced CMR. Furthermore, we correlated these CMR findings with the changes in post operative cardiac Troponin I. Our primary hypothesis was that off pump surgery results in reduced myocardial stunning (as measured by cine MRI) in the early post-operative period when compared to ONpump CABG (ONCABG) surgery. We further hypothesised that off pump surgery is superior to ONCABG with regards to the extent of permanent myocardial damage and that post-operative myocardial enzyme release reflects myonecrosis.

Ethics approval required

Old ethics approval format

Ethics approval(s) Not provided at time of registration

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

CABG surgery

Interventions

Single centre randomised trial comparing off pump (beating heart) versus conventional bypass coronary artery surgery.

Intervention Type

Procedure/Surgery

Primary outcome measure

1. Left ventricular function at one week post-op

- 2. LV function at six months post-op
- 3. Myocardial necrosis post-op

Secondary outcome measures No secondary outcome measures

Overall study start date 01/05/2002

01/05/2002

Completion date

01/10/2003

Eligibility

Key inclusion criteria

Aged less than 75 years
Isolated coronary grafting

Participant type(s)

Patient

Age group

Adult

Sex Both

Target number of participants 50

Key exclusion criteria

1. Age greater than 75 years (ten patients)

2. Ppre-existing Left Ventricular (LV) dysfunction (ejection fraction less than 20% by echocardiogram; four patients)

3. Involvement in other clinical trials (ten patients)

4. Typical MRI contraindications (e.g. pacemaker, severe claustrophobia etc.; total of nine patients)

5. Baseline creatinine more than 200 µmol/L (two patients)

Date of first enrolment 01/05/2002

Date of final enrolment 01/04/2003

Locations

Countries of recruitment England

United Kingdom

Study participating centre John Radcliffe Hospital Oxford United Kingdom OX3 9DU

Sponsor information

Organisation University of Oxford (UK)

Sponsor details University Offices Wellington Square Oxford England United Kingdom OX1 2JD +44 (0)1865 270143 research.services@admin.ox.ac.uk

Sponsor type University/education

Website http://www.ox.ac.uk

ROR https://ror.org/052gg0110

Funder(s)

Funder type Charity

Funder Name Wellcome Trust (UK) (grant ref: 066216)

Alternative Name(s)

Funding Body Type Private sector organisation

Funding Body Subtype International organizations

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	27/01/2004		Yes	No