

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 22/07/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 22/07/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 12/06/2015	Condition category 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
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 peri-operative 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 ON-pump 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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

1. Left ventricular function at one week post-op
2. LV function at six months post-op
3. Myocardial necrosis post-op

Key secondary outcome(s)

No secondary outcome measures

Completion date

01/10/2003

Eligibility**Key inclusion criteria**

1. Aged less than 75 years
2. Isolated coronary grafting

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Age greater than 75 years (ten patients)
2. Pre-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 $\mu\text{mol/L}$ (two patients)

Date of first enrolment

01/05/2002

Date of final enrolment

01/04/2003

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

John Radcliffe Hospital
Oxford
United Kingdom
OX3 9DU

Sponsor information

Organisation

University of Oxford (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

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?
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[Results article](#)

results

27/01/2004

Yes

No