

# 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

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<b>Registration date</b> 22/07/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 12/06/2015	<b>Condition category</b> 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

**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 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

### **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

**Completion date**

01/10/2003

**Eligibility****Key inclusion criteria**

1. Aged less than 75 years
2. 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. 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**

England

United Kingdom

**Study participating centre**

**John Radcliffe Hospital**

Oxford

United Kingdom

OX3 9DU

## **Sponsor information**

**Organisation**

University of Oxford (UK)

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**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?
<a href="#">Results article</a>	results	27/01/2004		Yes	No