

A randomised trial of conventional and off-pump coronary artery bypass grafting (CABG) on myocardial injury as assessed by multi-parametric magnetic resonance imaging (MRI) and specific biochemical markers.

Submission date 30/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/09/2005	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 30/08/2013	Condition category Surgery	<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

N0176113611

Study information

Scientific Title

Study objectives

1. To quantify both functional and irreversible myocardial injury after CABG, with and without cardiopulmonary bypass (CPB) using multiparametric cardiac MRI at the highest spatial resolution.
2. To quantify the pathophysiological significance of bio chemically defined myocardial injury with MRI determined grams of myocardial tissue loss after CABG, with and without CPB.
3. To define the power of these new MRI indices to predict functional recovery at 6 months post-surgical revascularisation.

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

Surgery: Coronary artery bypass grafting (CABG)

Interventions

Patients will be randomised to receive conventional CABG or off-pump CABG (OPCABG).

Intervention Type

Procedure/Surgery

Phase

Not Applicable

Primary outcome measure

1. Number and percentage of new left ventricular (LV) wall segments that are assessed as non viable by late Gd-DTPA MR imaging in both the conventional CABG and OPCABG groups
2. The distribution (regional versus global) of new non viable LV segments in both the conventional CABG and OPCABG groups
3. The extent of post operative rise in biochemical cardiac markers will be compared in the two surgical groups and will be correlated with the functional cardiac MR assessment.

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/06/2002

Completion date

30/09/2003

Eligibility**Key inclusion criteria**

90 patients undergoing CABG

Participant type(s)

Patient

Age group

Not Specified

Sex

Not Specified

Target number of participants

90 (70 study patients and 20 post MI patients)

Key exclusion criteria

Does not match inclusion criteria

Date of first enrolment

01/06/2002

Date of final enrolment

30/09/2003

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Department of Cardiovascular Medicine

Oxford

United Kingdom

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Sponsor information

Organisation

Department of Health

Sponsor details

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Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type

Government

Funder Name

Oxford Radcliffe Hospitals NHS Trust (UK) - Departmental resources

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