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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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/09/2005	**Overall study status** Completed	
Last Edited 30/08/2013	**Condition category** Surgery	

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
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Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
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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