Myocardial Injury following Coronary Artery bypass Surgery versus percutaneous coronary Angioplasty with stents: a randomised controlled trial using biochemical markers and cardiovascular magnetic resonance imaging

Submission date	Recruitment status No longer recruiting	Prospectively registered		
23/04/2006		Protocol		
Registration date	Overall study status	Statistical analysis plan		
06/06/2006	Completed	[X] Results		
Last Edited 24/01/2014	Condition category Circulatory System	[] Individual participant data		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

06/Q1606/19

Study information

Scientific Title

Acronym

MICASA

Study objectives

In patients with multivessel and/or left main Coronary Artery Disease (CAD), Percutaneous Coronary Intervention (PCI) compared with Coronary Artery Bypass Grafting (CABG) results in less frequent heart muscle injury, as measured by cardiac troponin I and delayed enhancement Magnetic Resonance Imaging (MRI). Secondarily, that percutaneous coronary intervention offers equivalent revascularisation compared with coronary artery bypass surgery as measured by MRI perfusion.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Oxfordshire Local Research Ethics Committee on the 17th March 2006 (ref: 06/Q1606/19).

Study design

Randomised clinical trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Multivessel coronary artery disease

Interventions

Coronary artery bypass grafting versus percutaneous coronary intervention.

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

The frequency of new myocardial injury following PCI and CABG as assessed by biochemical markers (troponin I) and MRI.

Secondary outcome measures

- 1. Total amount of new myocardial necrosis (in grams) assessed by MRI
- 2. Change in left ventricular function assessed by MRI

Overall study start date

01/06/2006

Completion date

31/12/2007

Eligibility

Key inclusion criteria

- 1. Patients with greater than or equal to two vessel CAD (greater than or equal to 50% stenosis) including the Left Anterior Descending (LAD), and/or a functionally significant left main stem stenosis of 50% or more
- 2. Equivalent revascularisation can be provided by PCI and CABG
- 3. Angina (stable or unstable), or documented silent ischaemia on functional stress testing

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

60

Kev exclusion criteria

- 1. Contraindication to aspirin or clopidogrel
- 2. Women of childbearing potential
- 3. Non-viable myocardium in the area subtended by diseased vessels
- 4. Patients requiring concomitant cardiac surgery
- 5. Acute myocardial infarction

Date of first enrolment 01/06/2006

Date of final enrolment 31/12/2007

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Department of Cardiology
Headington
United Kingdom
OX3 9DU

Sponsor information

Organisation

Oxford Radcliffe Hospitals NHS Trust (UK)

Sponsor details

Research and Development Manor House John Radcliffe Hospital Headley Way Headington England United Kingdom OX3 9DU

Sponsor type

Hospital/treatment centre

ROR

https://ror.org/03h2bh287

Funder(s)

Funder type

Funder Name

Cordis, a division of Johnson & Johnson Medical Ltd (UK) - Dr William van Gaal is funded by the Clinical Cardiology Research Scholarship

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	01/01/2011		Yes	No
Results article	results	08/02/2011		Yes	No
Results article	results	01/12/2011		Yes	No
Results article	results	01/06/2013		Yes	No