

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 23/04/2006	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 06/06/2006	Overall study status Completed	☐ Statistical analysis plan ☒ 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

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Additional identifiers

Protocol serial number
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). Secondly, 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).

Primary study design

Interventional

Study design

Randomised clinical trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key 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

United Kingdom

England

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

Sponsor information

Organisation
Oxford Radcliffe Hospitals NHS Trust (UK)

ROR
<https://ror.org/03h2bh287>

Funder(s)

Funder type
Industry

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

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