

The Coronary Artery Revascularisation in Diabetes trial

Submission date

14/01/2008

Recruitment status

No longer recruiting

☐ Prospectively registered

☒ Protocol

Registration date

02/04/2008

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

13/07/2012

Condition category

Nutritional, Metabolic, Endocrine

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Akhil Kapur

Contact details

London Chest Hospital
Barts and the London NHS Trust
Bonner Road
London
United Kingdom
E2 9JX
+44 (0)20 8983 2413
a.kapur@ic.ac.uk

Additional identifiers

Protocol serial number

46

Study information

Scientific Title

A prospective, randomised comparison of optimal coronary angioplasty with use of stenting and abciximab recommended versus up to date coronary artery bypass grafting in patients with diabetes mellitus suitable for either intervention

Acronym

CARDia trial

Study objectives

The aim of the CARDia trial is to establish whether optimal percutaneous coronary intervention (PCI) is a revascularisation strategy which is non-inferior to up-to-date coronary artery bypass grafting (CABG) in diabetic patients with multivessel or complex single vessel coronary artery disease with respect to the well established endpoints of all cause and vascular mortality, non-fatal myocardial infarction (MI) and stroke. There has to date been no prospective trial addressing this question specifically. This trial is designed to assess the hypothesis that optimal PCI is not inferior to up-to-date CABG.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Northern and Yorkshire Multi-centre Research Ethics Committee on the 21st August 2001 (ref: MREC1/3/24).

Primary study design

Interventional

Study design

Multi-centre, randomised, prospective comparison

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Diabetes mellitus

Interventions

Multi-centre, randomised, prospective comparison with predefined endpoints analysis at 30 days, 6 months, 1-year (primary endpoint), 2-year and 5-year follow-up.

Coronary artery bypass grafting (CABG) versus percutaneous coronary intervention (PCI). Total duration for follow up is five years.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Abciximab

Primary outcome(s)

Occurrence of the composite of all-cause death, non-fatal MI, non-fatal stroke at one year.

Key secondary outcome(s)

1. All individual components of the primary and major secondary endpoints at 30 days, six months, two years and five years
2. Death/MI/target vessel revascularisation (TVR) at six months for bare metal versus sirolimus stents
3. Death/MI/coronary vascular accident (CVA)/further revascularisation at one year for sirolimus stents versus CABG
4. Severe bleeding complications at 30 days
5. New requirement for permanent dialysis
6. Neurological morbidity
7. Quality of life (measured with the EuroQoL (EQ5D) and cognitive assessment questionnaires), assessed at screening, 30-day and six-month follow-up. The EQ5D will also be assessed at 12 months, two years and five years follow-up.
8. Cost difference between treatments
9. Change in left ventricular (LV) function

Completion date

30/06/2012

Eligibility

Key inclusion criteria

General inclusion criteria:

1. Patients with type I or type II diabetes mellitus (no medication, oral medication, insulin therapy) defined by World Health Organization (WHO) criteria for those patients not on medical treatment, and
2. Coronary stenoses of greater than 50% severity in greater than or equal to two or more coronary arteries or single significant stenosis in proximal left anterior descending (LAD) before the first septal branch or complex bifurcation lesions in any major epicardial vessel, and
3. Stable (Canadian Cardiovascular Society class I - IV) or unstable (Braunwald class IB, IC, IIB, IIC, IIIB, IIIC alongside any intensity of treatment [1 to 3]) angina pectoris or patients with anginal equivalent and evidence of ischaemia (e.g. treadmill exercise test, radionuclide perfusion scanning, stress echocardiography), and
4. Suitable for revascularisation using optimal PCI (including abciximab and stenting) or up-to-date CABG
5. Written informed consent
6. Agreement between cardiothoracic surgeon and cardiologist that the selected case fulfils both inclusion and exclusion criteria
7. Age greater than 18 years and less than 80 years, either sex

Angiographic inclusion criteria:

1. Multivessel disease with one or more significant stenoses in at least two major epicardial coronary arteries (LAD, left circumflex [CX] and right coronary artery [RCA]) or single vessel complex disease defined as:
 - 1.1. A proximal LAD lesion before the first septal branch, or
 - 1.2. A bifurcation lesion involving a side branch and a main epicardial vessel provided they supply different territories

2. Total occlusions of one major epicardial vessel or side branch can be included as long as one other major vessel has a significant stenosis
3. A significant stenosis is defined as a stenosis of at least 50% but less than 100% in luminal diameter (in at least one view, on visual interpretation or by qualitative comparative analysis [QCA])
4. Stenting in lesions with a bifurcation, thrombus, calcification or very long obstruction (greater than 20 mm) is left to the operators discretion
5. The number of stents implanted per patient is not restricted

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

General exclusion criteria:

1. Inability to consent
2. Current participation in another study
3. Greater than 80 years and less than 18 years
4. Congenital heart disease
5. History of previous PCI or CABG
6. When complete follow up over a period of two years is, in the judgement of the investigator, unlikely
7. Inadequate quality of saphenous vein or arterial conduit material
8. Serum creatinine of greater than 250 $\mu\text{mol/l}$ or episode of renal dialysis within the 30 days prior to randomisation. However, those on established dialysis greater than six months are eligible for inclusion
9. Q-wave myocardial infarction within the six weeks prior to randomisation
10. Significant valve disease likely to result in requirement for surgery now or within the next five years
11. Other disease shortening life expectancy to less than 12 months
12. Persistence of severe uncontrolled hypertension (blood pressure [BP] greater than 200/120) within the 48 hours prior to randomisation
13. Administration of oral anticoagulation within seven days of planned revascularisation or International normalised ratio (INR) of greater than or equal to 1.4 with ongoing oral anti-coagulation treatment
14. Blood dyscrasia (platelets less than 100, haemoglobin [Hb] less than 8 g/dl, INR greater than 1.4, activated partial thromboplastin time [APTT] greater than 2 x normal, leukocyte count less than $3.5 \times 10^9/\text{l}$, neutrophil count less than $1 \times 10^9/\text{l}$)
15. Intolerance or contraindication to aspirin, clopidogrel or abciximab

Angiographic exclusion criteria:

1. Left main stem stenosis of 50% or more
2. Intention to treat more than one totally occluded major epicardial vessel

Date of first enrolment

01/01/2002

Date of final enrolment

30/06/2012

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

London Chest Hospital

London

United Kingdom

E2 9JX

Sponsor information

Organisation

Hammersmith Hospitals NHS Trust (UK)

ROR

<https://ror.org/05jg8yp15>

Funder(s)

Funder type

Industry

Funder Name

Cordis Johnson and Johnson (UK)

Funder Name

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 after 1 year	02/02/2010		Yes	No
Results article	substudy results	01/12/2011		Yes	No
Protocol article	protocol	01/01/2005		Yes	No