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The Coronary Artery Revascularisation in Diabetes trial

Submission date	Recruitment status
14/01/2008	No longer recruiting
Registration date	**Overall study status**
02/04/2008	Completed
Last Edited	**Condition category**
13/07/2012	Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
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).

Study design
Multi-centre, randomised, prospective comparison

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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

Secondary outcome measures
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

Overall study start date
01/01/2002

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
600

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 iu/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 x 10^9/l, neutrophil count less than 1 x 10^9/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
England

United Kingdom

Study participating centre
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Sponsor information

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05jg8yp15

Funder(s)

Funder type
Industry

Funder Name
Cordis Johnson and Johnson (UK)

Funder Name
Eli Lilly and Company Limited (UK)

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?
Protocol article	protocol	01/01/2005		Yes	No

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