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Coronary artery grafting in high risk patients randomised to off-pump or on-pump surgery

Submission date 28/07/2008	**Recruitment status** Stopped	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data [_] Record updated in last year
Registration date 31/10/2008	**Overall study status** Stopped	
Last Edited 12/06/2015	**Condition category** Circulatory System	

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
MRC ref: G0700469

Study information

Scientific Title
Coronary artery grafting in high risk patients randomised to off-pump or on-pump surgery

Acronym
CRISP

Study objectives
Off-pump coronary artery bypass grafting (OPCABG) reduces mortality and morbidity in high risk patients, without a higher risk of reintervention, when compared to on-pump coronary artery bypass grafting (ONCABG).

More details can be found at http://www.mrc.ac.uk/ResearchPortfolio/Grant/Record.htm?GrantRef=G0700469&CaseId=9693

Ethics approval required
Old ethics approval format

Ethics approval(s)
Application has been submitted to the Scotland A Research Ethics Committee (ref: 08/MRE00/58). Approval pending as of 28/07/2008.

Study design
International multicentre open randomised controlled trial

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
Coronary heart disease

Interventions
This study is an international, multicentre open randomised controlled trial, across 40 centres: 20 in the UK and 20 overseas. Trial patients will be randomised to:
1. CABG without cardiopulmonary bypass, i.e. off-pump CABG (OPCABG) on the beating heart, via a median sternotomy incision

2. CABG with cardiopulmonary bypass i.e. on-pump CABG (ONCABG) on a chemically arrested heart, via a median sternotomy incision

Total duration of follow-up is 1 year post-surgery.

Intervention Type
Procedure/Surgery

Primary outcome measure
The primary outcome is a composite endpoint of death or serious morbidity (CRISPS). This is made up of the following:
1. Death after cardiac surgery within 30 days of the operation from any cause
2. New onset renal failure requiring renal replacement therapy up to and including 30 days of the operation
3. Myocardial infarction up to and including 30 days of the operation
4. Stroke up to and including 30 days of the operation
5. Prolonged ventilation greater than or equal to 96 hours during the index hospital admission
6. Sternal wound dehiscence requiring non-pharmacological intervention up to and including 30 days of the operation

Secondary outcome measures
1. Duration of intensive care stay
2. Duration of hospital stay
3. Survival, free from death or serious morbidity at one year
4. Resource use (hospital and other healthcare resources) during one year
5. Quality of life at one year: Rose Angina Questionnaire (short), EuroQol EQ-5D, the Coronary Revascularisation Outcome Questionnaire (CROQ; UK patients only)
6. Cost-effectiveness

Data will be collected on events between discharge and 30 days at a routine follow-up appointment 4 - 8 weeks after discharge. Questionnaires will be completed by the patient before surgery, at the 4 - 8 week follow-up appointment, and will be posted to patients for completion at 1 year post-surgery.

Overall study start date
01/01/2009

Completion date
24/03/2011

Reason abandoned (if study stopped)
Lack of funding/sponsorship

Eligibility

Key inclusion criteria
Current information as of 05/03/2010:
Patients having isolated CABG surgery will be eligible if they satisfy the following criteria:
1. Euroscore ≥5

2. Non-emergency surgery
3. Operation to be carried out via a median sternotomy
4. Written informed patient consent

Initial information at time of registration:
Patients having isolated CABG surgery will be eligible if they satisfy the following criteria:
1. Patients (male or female) aged greater than or equal to 70 years
2. Male patients under 70 years of age with moderate or poor left ventricular function (ejection fraction less than 50%)
3. Euroscore greater than or equal to 5
4. Non-emergency surgery
5. Operation to be carried out via a median sternotomy
6. Written informed patient consent

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
5,420 participants

Key exclusion criteria
Current information as of 05/03/2010:
1. Euroscore <5
2. Emergency operation (immediate revascularisation for haemodynamic instability)
3. Concomitant cardiac procedure with CABG
4. Operation to be carried out via an incision other than a median sternotomy (e.g. anterolateral left thoracotomy)
5. Known contraindication to ONCABG or OPCABG (e.g. calcified aorta, calcified coronaries, small target vessels)

Initial information at time of registration:
1. Male patient under 70 years of age with good left ventricular function (ejection fraction greater than 50%)
2. Euroscore less than 5
3. Emergency operation (immediate revascularisation for haemodynamic instability)
4. Concomitant cardiac procedure with CABG
5. Operation to be carried out via an incision other than a median sternotomy (e.g. anterolateral left thoracotomy)
6. Contraindication to ONCABG or OPCABG (e.g. calcified aorta, intramuscular left anterior descending [LAD], calcified coronaries, small target vessels)

Date of first enrolment
01/01/2009

Date of final enrolment

24/03/2011

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
John Radcliffe Hospital
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Sponsor information

Organisation
University of Oxford (UK)

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Sponsor type
University/education

Website
http://www.ox.ac.uk

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
Medical Research Council (MRC) (UK) (ref: G0700469)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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	01/07/2014		Yes	No