

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

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

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
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.

Primary study design

Interventional

Study design

International multicentre open randomised controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre

John Radcliffe Hospital

Oxford

United Kingdom

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Sponsor information

Organisation

University of Oxford (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, Medical Research Committee and Advisory Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

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	01/07/2014		Yes	No