

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

<b>Submission date</b> 28/07/2008	<b>Recruitment status</b> Stopped	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 31/10/2008	<b>Overall study status</b> Stopped	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 12/06/2015	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

**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  $\geq 5$

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

Oxford

United Kingdom

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## Sponsor information

### Organisation

University of Oxford (UK)

### Sponsor details

Clinical Trials and Research Governance

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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?
<a href="#">Results article</a>	results	01/07/2014		Yes	No