ISRCTN84724990 https://doi.org/10.1186/ISRCTN84724990

Coronary artery bypass graft (CABG) off- or on-pump revascularisation study

Submission date 04/02/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 04/02/2008	**Overall study status** Completed	
Last Edited 03/04/2019	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.ccc.mcmaster.ca/coronary.htm

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00463294

Secondary identifying numbers
MCT-85214; 5999

Study information

Scientific Title
Coronary artery bypass graft (CABG) off- or on-pump revascularisation study

Acronym
CORONARY

Study objectives
Primary hypothesis:
In patients undergoing coronary artery bypass graft (CABG) surgery, off-pump CABG surgery compared to on-pump CABG surgery reduces major clinical vascular events in the short term (30 days) and these benefits are maintained at long term (5 years).

Secondary hypothesis:
In patients undergoing CABG surgery, off-pump CABG surgery compared to on-pump CABG surgery reduces costs in the short term (30 days) and at long term (5 years).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from:
1. Canada: Research Ethics Board of Hamilton Health Sciences/McMaster University, Hamilton, Ontario on the 30th March 2007 (final approval for pilot) and 19th June 2007 (re-consent for long term follow-up) (ref: 06-045)
2. Brazil: Comite de Etica em Pesquisa, Institute Dante Pazzanese on the 6th November 2007 (ref: CEP 3581)
3. Colombia: Comité de Ética en Investigación , Fundacion Cardiovascular Del Oriente Colombiano, Floridablanca (SS) on the 23rd January 2008
4. France: Comité de Protection des Personnes, CHU-Hôpital Saint Jacques on the 26th June 2007 (ref: 07/446)
5. Turkey: Research Ethics Committee of Medical Faculty, Ankara University, Ankara on the 7th January 2008 (ref: 123-3353)
6. Chile: Gobierno De Chile, Servicio de Salud Metropolitano Oriente, Comité de Ética Científico, Santiago on the 20th January 2008
7. China: Ethics Committee FuWai Hospital, Beijing in May 2007
8. Czech Republic: Eticka Komise, Fakulni nemocnice Kralovske Vinohrady, Prague on the 9th January 2008
9. India: Ethics Committee All India Institute of Medical Sciences, Delhi on the 10th April 2008
10. Italy: Comitao Etico Intraziendale, Azienda Ospedaliera S. Croce e Carle, Cuneo on the 4th April 2008
11. Poland: Niezna Komisia Bioetyczna, Akademia Medyczna, Gdansk on the 15th May 2008
12. Ukraine: Komitet z medicnoi etiki, M.M. Amosov Government Facility, National Institute of Cardio-vascular Surgery on the 26th June 2008
13: United Kingdom: MREC approved (ref: 08/H0604/48)

Ethics approval pending as of 26/04/2010 from:
14. Slovak Republic
15. Argentina
16. Netherlands

Study design
International unblinded multicentre two arm randomised parallel surgical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Coronary artery disease requiring isolated coronary artery bypass graft (CABG)

Interventions
Coronary artery bypass graft (CABG) surgery with or without cardio-pulmonary bypass (CPB) machine:
1. Experimental group: CABG without use of CPB
2. Control group: CABG with the use of CPB

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Intervention Type
Other

Phase
Not Specified

Primary outcome measure
1. The occurrence of the composite of total mortality, stroke, nonfatal myocardial infarction [MI], or new renal failure at 30 days post CABG surgery
2. The occurrence of the composite of total mortality, stroke, nonfatal MI, new renal failure, or repeat coronary revascularisation (i.e. coronary artery bypass surgery or percutaneous coronary intervention) over 5 years after randomisation

Secondary outcome measures
1. The assessment of total costs and resources consumption at 30 days after CABG surgery
2. The assessment of total costs and resources consumption at 5 years after CABG surgery

Overall study start date
01/10/2007

Completion date
31/05/2014

Eligibility

Key inclusion criteria
1. Require isolated CABG with median sternotomy
2. Provide written informed consent
3. 21 years of age and older, either sex
4. Have one risk factor or more:
4.1. Greater than or equal to 70 years age
4.2. Peripheral vascular disease (previous peripheral bypass or amputation or ankle brachial index [ABI] less than 0.80)
4.3. Cerebrovascular disease (history of stroke, transient ischaemic attack [TIA], carotid stenosis greater than 70%)
4.4. Renal insufficiency (creatinine above upper limit of normal)
4.5. Greater than 60 years of age with one of the following:
4.5.1. Diabetes (oral hypoglycaemic agent and/or insulin)
4.5.2. Urgent revascularisation (waiting in hospital)
4.5.3. Left ventricular ejection fraction less than 35%
4.5.4. Current or recent smokers (within 1 year of randomisation)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 4700; UK Sample Size: 250

Key exclusion criteria
1. Concomitant cardiac procedure associated with CABG
2. Contra-indications to off-pump CABG or on-pump CABG (calcified aorta, intramuscular left anterior descending [LAD], calcified coronaries, small target vessels)
3. Concomitant life-threatening disease likely to limit life expectancy to less than 2 years
4. Prior enrolment in this trial
5. Emergency CABG surgery (immediate revascularisation for haemodynamic instability)
6. Redo CABG

Date of first enrolment
01/10/2007

Date of final enrolment
31/05/2014

Locations

Countries of recruitment
Argentina

Brazil

Canada

Chile

China

Colombia

Czech Republic

France

India

Italy

Netherlands

Poland

Slovakia

Türkiye

Ukraine

United Kingdom

Study participating centre
Hamilton General Hospital
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Sponsor information

Organisation
Population Health Research Institute (PHRI) (Canada)

Sponsor details
McMaster University, General Site
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Sponsor type
Research organisation

Website
http://www.ccc.mcmaster.ca/

ROR
https://ror.org/03kwaeq96

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-85214)

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	01/01/2012		Yes	No
Protocol article	sub-study protocol	18/04/2012		Yes	No
Results article	results	19/04/2012		Yes	No
Results article	results	28/03/2013		Yes	No
Results article	results	04/06/2014		Yes	No
Results article	results	01/11/2014		Yes	No
Results article	results	15/12/2016		Yes	No