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Total arterial grafting versus internal mammary and saphenous vein grafting for coronary artery bypass graft surgery

Submission date 17/11/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 08/12/2009	**Overall study status** Completed	
Last Edited 12/11/2015	**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
REB 2004-121

Study information

Scientific Title
A randomised clinical trial comparing total arterial grafting versus internal mammary and saphenous vein grafting for coronary artery bypass graft surgery

Study objectives
Total arterial grafting (TAG) will result in improved graft patency and patient outcomes when compared to conventional (coronary artery bypass graft) CABG surgery using the left internal mammary artery (LIMA) and saphenous vein (SV).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Capital Health Authority, New Halifax Infirmary Research Ethics Board (REB), 21/12/2004, ref: REB 2004-121

Study design
Randomised unblinded controlled clinical 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
Ischaemic heart disease

Interventions
Consented patients will undergo CABG surgery using TAG (experimental group) or LIMA/SV (control group) based on the randomisation assignment and followed for 6 months post surgery with coronary angiography.

Surgical technique:
Standard induction of anaesthesia will be performed using a combination of benzodiazepines and opioid narcotics. Once intubated, appropriate anesthetic management will be carried out

with a combination of muscle relaxant, opioid narcotic and inhaled halogenated and non-halogenated gases. All surgical interventions will be carried out in a standardised fashion to minimise intra-operative patient-to-patient variability.

Post-operative management:
All post-operative cardiac surgery patients will be taken immediately to a dedicated cardiovascular intensive care unit. Each patient is required to meet standard criteria both prior to extubation and prior to transfer to the intermediate-care unit. Discharged patients will be transferred to an intermediate-care unit or general-care ward under the care of the same team, and all patients will be monitored continuously for a minimum of 24 hours. Serial electrocardiograms will be obtained pre-operatively, at day 1 post-operatively and at the time of discharge. Routine medications to all enrolled patients will include acetylsalicylic acid (ASA), ß-blockers, lipid-lowering agents and angiotensin converting enzyme inhibitors unless contraindicated.

CT angiography:
All patients will undergo CT angiography at 6 months post-coronary artery bypass graft operation. This will be performed on a 64 slice multidetector CT scanner (Siemens Sensation 64, Erlangen, Germany), using the following scan parameters: 330 ms gantry rotation, detector collimation 32 x 0.6 mm (with a rapidly alternating focal spot resulting the acquisition of 64 slices per gantry rotation with effective special resolution of 0.4 mm), tube voltage 120 kV, maximum obtainable tube current (800 - 900 mAs) scanning in a caudo-cranial direction. 100 mL of contrast agent (Isovue 370, Bracco, Italy) will be injected into a right antecubital vein via an 18-guage cannula at a flow rate of 5 mL/s, followed by 40 mL of normal saline bolus chaser at a rate of 5 mL/s. All patients with heart rate greater than 65 beats per minute will, unless contra-indicated, receive beta blocker in the form of 50 mg oral metoprolol, 0.2 µg of sublingual glycerol trinitrate +/- 1 - 2 mg oral lorazepam prior to being scanned in order to reduce heart rate and maximise the lumen diameter of the coronary artery bypass grafts.

Intervention Type
Procedure/Surgery

Primary outcome measure
Six-month graft patency in patients who undergo TAG compared to those who undergo conventional coronary artery revascularisation with LIMA/SV grafts. Grafts will be assessed as patent, occluded or stenosed greater than 50%. For grafts with sequentially supply more than one vessel, each inter-anastomotic segment will be assessed separately.

Secondary outcome measures
Rates of adverse cardiovascular events in patients who undergo TAG compared to those who undergo conventional coronary artery revascularisation with LIMA/SV grafts. Results will be reported separately and as composite outcomes. Adverse cardiovascular events will be defined as:
1. Short term event: in-hospital mortality and in-hospital morbidity:
1.1. All cause mortality with the cause of death recorded
1.2. Morbidity: peri-operative myocardial infarction, re-intervention (percutaneous coronary intervention [PCI] or CABG), low output syndrome, prolonged mechanical ventilation, sternal wound infection and prolonged length of hospitalisation
2. Late adverse cardiovascular events defined as:
2.1. All cause mortality
2.2. Readmission to hospital for cardiac reason

Overall study start date
01/01/2009

Completion date
01/06/2010

Eligibility

Key inclusion criteria
1. Consecutive patients between the ages of 60 and 75 years of age*, either sex
2. Undergoing non-emergent isolated CABG surgery for 3 vessel coronary disease
3. Have not already been enrolled in another study

*The average age of patients undergoing CABG surgery at the QEII is approximately 70 with 50% of patients between the age restrictions. The age limit of 75 is an attempt at increasing long-term follow-up of patients which would be limited in octogenarians.

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Scheduled to undergo emergency or emergency salvage surgery
2. Angiographically ungraftable coronary territories
3. Prior surgical coronary revascularisation
4. Evidence of varicose veins on pre-operative physical examination which would preclude the use of the greater saphenous vein as a graft conduit
5. Previous radiation treatment to their chest area (which would make the utility of internal mammary arteries questionable)
6. Relative contraindications to computed tomography (CT) angiography such as pregnancy, chronic renal insufficiency (creatinine greater than 120 umol/L), or allergy to contrast media

Date of first enrolment
01/01/2009

Date of final enrolment
01/06/2010

Locations

Countries of recruitment
Canada

Study participating centre
New Halifax Infirmary
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Sponsor information

Organisation
Capital Health Authority, New Halifax Infirmary (Canada)

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Sponsor type
Hospital/treatment centre

Website
http://www.cdha.nshealth.ca

ROR
https://ror.org/05m7vf540

Funder(s)

Funder type
University/education

Funder Name
Dalhousie University (Canada) - Department of Surgery

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	08/01/2015		Yes	No