ISRCTN84091290 https://doi.org/10.1186/ISRCTN84091290

A Randomised Controlled Trial Comparing Conventional Coronary Artery Bypass Graft Surgery with a Composite Arterial Graft Technique

Submission date 29/09/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 29/09/2006	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 28/04/2015	**Condition category** Surgery	[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0054174154

Study information

Scientific Title
A Randomised Controlled Trial Comparing Conventional Coronary Artery Bypass Graft Surgery with a Composite Arterial Graft Technique

Study objectives
The aim of this proposed study is to compare composite arterial bypass grafting with conventional surgery in the management of patients requiring three or more distal anastamosis sites. Patients referred for isolated multi-vessel coronary bypass graft (CABG) surgery under the care of participating surgeons will be screened for trial eligibility. Patients will be recruited if they are referred to the participating surgeon for isolated multi-vessel CABG with an intention to fashion at least three distal anastamosis sites. Patients will not be included in the trial if they require emergency CABG with evidence of active ischaemia at rest or haemodynamic compromise. They will also be excluded if they have poor left ventricular function (ejection fraction <25%), proposed surgical or other intervention on a cardiac valve, great vessel disease, previous stroke, non-cardiac disease limiting survival potential over 1 year, subclavian or other vascular disease compromising the use of an internal mammary artery (IMA) pedicle graft, absence of graft conduit material required for either surgical approach and intention to perform bilateral IMA pedicle grafts and high risk of complication from subsequent follow-up diagnostic cardiac catheterisation. Patients that consent for the study will be randomised in equal proportions into the two experimental groups.

1. The principal aim of this study is to compare two current techniques in performing Coronary Artery Bypass Graft CABG outcomes in terms of:
1.1 The impact of the procedure on angina symptoms
1.2 Continued function of the bypass grafts in terms of their ability to provide blood to the heart (grafts patency)
2. The secondary aims of the study is to compare the following outcomes between the composite arterial technique versus conventional arterial graft procedures for coronary bypass surgery:
2.1 All cause mortality
2.2 Non-fatal myocardial infarction (heart attacks)
2.3 Cerebrovascular accident (stroke)
2.4 Procedure duration

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled 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
Surgery: Coronary artery bypass graft (CABG)

Interventions
The composite arterial graft group will be given a LIMA pedicle and free radial artery graft conduit system with one or more sequential anastamoses (a series of distantly placed connections) as required (Note: The use of two radial artery trunks - each with its own anastamosis on the left internal mammary artery (LIMA) trunk will not be permitted in this study). The conventional surgery group will be given a unique conduit trunk for each distal anastamosis (distantly placed connection). The conventional surgical strategy must include the use of a LIMA pedicle graft, usually to the LAD. The choice of other grafts is at the discretion of the operator and radial or venous grafts may be used. Following randomisation patients will be listed for surgery. All participating surgeons are experienced in the performance of both types of CABG operation and will perform the allocated procedure according to best current local practice. All patients will be followed up for 6 months at which point they will undergo elective scheduled angiography for the assessment of graft patency. Event tracking will begin at randomisation and continue through the observed follow-up to 6 months. All analyses will be performed on an intention to treat basis, including all patients randomised, irrespective of subsequent treatment or events. The study will compare the impact of both procedures on patient self reported angina symptoms. Cardiac related health status will be assessed at baseline and at 6 months after intervention using the Seattle Angina Questionnaire (SAQ), a 19-item self administered questionnaire quantifying 5 clinically relevant domains of cardiac related health status: physical limitation, angina stability, angina frequency, treatment satisfaction and disease perception/quality of life. Scores range from 0 to 100 for each domain with higher scores indicating better functioning (that is, less physical limitation and less frequent angina). A clinically important change is between five and eight points. At 6 months follow-up, the proportion of distal anastamoses that are patent with TIMI 3 flow into the distal native vessel will be assessed by cardiac catheterisation. Angiograms will be reviewed and scored by the consensus of a panel of trial investigators that would include a cardiologist and a surgeon. Data will be collected into a database on: all cause mortality, non fatal myocardial infarction (heart attacks), cerebrovascular accident (strokes), and duration of procedure. Results from a previous study (SOS) by the principal investigator indicated that at 6 month follow-up CABG patients had a mean SAQ scores in the range 75-89 in the three domains under consideration representing mean changes from baseline in the range 17-35. Power calculations were based on the most demanding scenario, assuming a mean change from baseline of 15 points with a standard deviation of 7. An absolute difference of 2.4 in SAQ change score could be detected at 80% power (alpha error 0.05) from 270 patients in each arm of the study. The four surgeons involved in this trial performed more than 550 isolated CABG operations in the last year alone. The vast majority of these involved 3 or 4 graft procedures. The study timeline will include a 4 month

start up phase for the obtaining of ethical approval, institutional approval and training of the study personnel. The target recruitment period is 18-24 months. A 6 months period after the last CABG is required to complete follow up angiograms

Intervention Type
Procedure/Surgery

Phase
Not Specified

Primary outcome measure
This will compare the impact of the procedures on:
1. Patient self reported angina symptoms assessed at baseline and at 6 months after intervention using the Seattle Angina Questionnaire with relevant domains of cardiac-related health status: physical limitation, angina stability, angina frequency, treatment satisfaction and disease perception/quality of life. 2. A 6 month angiographic follow-up assessment to establish the proportion of distal anastamosis sites that are patent with TIMI 3 flow into the distal native vessel.

Secondary outcome measures
1. All cause mortality
2. Non-fatal myocardial infarction (including routine enzyme screening post CABG)
3. Cerebrovascular accident (strokes)
4. Procedure duration.

Overall study start date
01/11/2005

Completion date
30/11/2007

Eligibility

Key inclusion criteria
300 patients will be recruited and randomly allocated in equal proportions to elective composite graft or conventional coronary artery bypass graft surgery. No randomised trials have been performed on all age groups of patients undergoing elective bypass surgery using composite graft techniques versus conventional bypass graft surgery. A recent randomised study comparing Saphenous vein grafts and radial artery conduits included angiographic follow-up at 1 year. 4 Graft failure rates were comparable at around 15%. Assuming that LIMA failure rates are more favourable (2%) the proportion of failed distal anastomosis sites in 100 patients with 3 bottom ends would be 2 from LIMA failure and 30 from other conduits - a rate of 32/300 or 10%. For patients with 4 bottom ends the figures would be 47/400 or 12%. If there is an equal proportion of 3 and 4 graft cases then a failure rate of 11% can be assumed for the conventional surgery group. From this data, a sample size of 300 patients would provide a denominator of 3.5 x 300 = 1050 anastomoses. Assuming 90% of patients yield angiographic images at follow-up (allowing for death, failure to consent and angiographic problems) the study would have an 80% power to detect a failure rate of 17% in the composite group (alpha error =0.05). Power for the angina outcome has been presented at the Seattle Questionnaire. All patients who fulfill the eligibility criteria will be approached by the participating surgeons and will be screened for trial eligibility. A patient information sheet will also be provided. Only patients who provide written

informed consent prior to the procedure may be included. A copy of the written consent will be stored in the medical records, the study file and a copy will be given to the patient. The investigator will sign in the case record form that informed written consent has been obtained and the date consent was obtained. Informed consent will involve individual discussion with the patient about the nature of the procedures in a language that is easy to comprehend. The potential risks and benefits will be explained to the patient and they will be given time to make a decision about participation. It will be made clear that there is a random allocation to the two groups (composite versus conventional coronary artery bypass graft surgery) and that the patient or the physician does not decide which group they are allocated. It will be made clear that the patient can withdraw at any time from the research and does not have to give an explanation and it will not affect their medical care in any way. It will be recommended that the patient is given 24 hours to think about participation and discussing with family, friends or other healthcare professionals before signing the consent form. Referral to a participating surgeon for isolated multi-vessel CABG with an intention to fashion at least three distal anastomosis sites.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
300

Key exclusion criteria
1. Any contraindication to trial entry based on the clinical judgment of the responsible surgeon eg anticipated difficulty in surgical access, surgery planned as an emergency CABG on admission, and patients on inotropic support or cardiogenic shock
2. Re-operation
3. Proposed surgical or other intervention on a cardiac valve, great vessel, myocardial substance or other cardiovascular structure
4. Previous CVA/TIA within the last 6 months
5. Significant problem with graft material eg inability to use IMA graft, or absence of graft conduit material
6. Intention to perform bilateral IMA pedicle grafts
7. High risk of complication from subsequent follow-up diagnostic cardiac catheterisation including peripheral vascular disease, established renal dysfunction (serum creatinine >200 µmol /L or functioning transplant), allergy to radiographic contrast and previous angiographic complication or difficulty.
8. Recent involvement in another study (past 30 days etc)

Date of first enrolment
01/11/2005

Date of final enrolment
30/11/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Cardiothoracic Centre
Liverpool
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Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2006 Update - Department of Health

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Funder(s)

Funder type
Government

Funder Name
The Cardiothoracic Centre Liverpool NHS Trust (UK), NHS R&D Support Funding

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