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A randomised study comparing three types of vein harvesting method for coronary artery bypass surgery

Submission date
30/04/2014

Recruitment status
No longer recruiting

Registration date
18/09/2014

Overall study status
Completed

Last Edited
27/06/2017

Condition category
Surgery

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
A coronary artery bypass graft (CABG) is a surgical procedure used to treat coronary heart disease. In coronary heart disease, the major arteries supplying blood to the heart become narrowed, or blocked, due to the build-up of fatty deposits (plaques). This condition is called atherosclerosis. A CABG is used to improve both blood and oxygen supply to the heart and reduce the risk of a heart attack. It involves taking a blood vessel from elsewhere in the body usually from the chest, arm or leg and attaching it above and below the portion of coronary artery that has been affected by atherosclerosis. The aim of this study is to compare three different ways to take out a leg vein (referred to as harvesting the vein) for CABG to see which one is the best technique.

Who can participate?
Adults who are at least 18 and undergoing CABG at the University Hospital of South Manchester (UK)

What does the study involve?
Patients are randomly allocated to undergo one of the three vein removal techniques and the removed vein is then used for CABG. A small sample of the vein in each case is taken to laboratory for further cell studies to look at how the cells that make up the vein have reacted to the different vein removal techniques used. The patients are also contacted by telephone every 3 months for the first year after surgery and then again 3 years and 5 years after the operation. On each of these occasions, a member of the research team asks them to complete a questionnaire about their progress.

What are the possible benefits and risks of participating?
This study will provide data which will guide selection of the best vein harvesting technique in future clinical practice. Possible postoperative risks include wound infection, wound gapping, pain and serous discharge (weeping) from the wound site.

Where is the study run from?
Cardiothoracic department and Transplant research laboratory, University Hospital of South Manchester NHS Foundation Trust, Manchester (UK)

When is the study starting and how long is it expected to run for?
January 2011 to January 2015

Who is funding the study?
1. NIHR CAT Clinical Research Fellowship (UK)
2. University Hospital of South Manchester (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomised study comparing Vein Integrity and Clinical Outcomes (VICO) in open vein harvesting and two types of endoscopic vein harvesting for Coronary Artery Bypass Surgery - The VICO trial.

Acronym
VICO

Study objectives
1. Is there any difference in [DOE1] vein integrity following vein harvesting with open vein harvesting (OVH), closed-tunnel endoscopic vein harvesting (CT-EVH) and open-tunnel endoscopic vein harvesting (OTEVH)?
2. Are there any differences in clinical outcomes (ie mortality, graft failure, myocardial infection) between OVH, CT-EVH and OT-EVH?
3. Is there any association between [DOE2] vein integrity and clinical outcomes?
4. Are there any differences in patient reported outcomes (ie health-related quality of life and satisfaction) between OVH, CT-EVH and OT-EVH?
5. Are there any differences in cost between these techniques?

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Committee (NREC), ref: 12/NW/0572

Study design
Single-center 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 to request a patient information sheet

Health condition(s) or problem(s) studied
Coronary artery bypass surgery

Interventions
Computer block randomisation assigned the patients to undergo an open vein harvesting (control group: n=150), Closed tunnel CO2 endoscopic vein harvesting (n=150) and Open tunnel CO2 endoscopic vein harvesting (n=150). The assignment number will be concealed in a closed envelope separately for each patient by an independent Statistical team member who are not involved in this study or involved to the research group. The envelope will be delivered and opened by the surgical team (as late as possible), once the patient is anaesthetised for the surgery on the operating room.

Control group: Will receive a standard open vein harvesting with a long incision on their donor leg.
Group 1 : Closed tunnel : Will receive a endoscopic vein harvesting (Maquet EVH device) of two or three 2-3 cm cut in their donor leg.
Group 2: Open tunnel : Will receive a endoscopic vein harvesting (Sorin EVH device) of two or three 2-3 cm cut in their donor leg.

All the patients in this study will be donoating 3 cm (1cm x3) of vein samples will be collected from each patient during the surgery and will be send to the laboratory for tissue investigations.

All the patients will be followed up until their discharge from day 1 of their operation. They will be contact on the telephone at 3 month intervals within the first year, and then at 1,3 and 5 years.

Intervention Type
Procedure/Surgery

Phase
Not Applicable

Primary outcome measure
Long saphenous vein integrity, as indicated by the level of histological damage

Secondary outcome measures
1. Post-surgical clinical outcomes, specifically major adverse cardiac events such as reoccurrence of angina, myocardial infarction, vein graft failure, mortality and wound complications
2. Patient reported outcomes: generic health related quality of life
3. Health economic analysis: the costs and effects of the three approaches to vein harvesting

Overall study start date
01/01/2011

Completion date
01/01/2015

Eligibility

Key inclusion criteria
1. Patients undergoing CABG surgery at the University Hospital of South Manchester
2. Aged 18 or over
3. Written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
300 patients for initial recruitment and the results will be analysed and discussed in the ethics meeting. If there is a need, the study will be continued until 450 patients recruitment

Key exclusion criteria
1. Any patient who refuses or withdraws the consent
2. Patients undergoing emergency surgery or a contra-indication to a technique including varicose vein on the long saphenous vein, small or thin legs and a superficial LSV

Date of first enrolment
01/01/2011

Date of final enrolment
01/01/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Wythenshawe Hospital
South Manchester
United Kingdom
M239LT

Sponsor information

Organisation
University Hospital of South Manchester NHS Foundation Trust (UK)

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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00he80998

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
NIHR CAT Clinical Research Fellowship (UK)

Funder Name
University Hospital of South Manchester (UK)

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	31/10/2017		Yes	No