

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 18/09/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 27/06/2017	Condition category Surgery	<input type="checkbox"/> 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?

Prof. Nizar Yonan

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Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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 donating 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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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

United Kingdom

England

Study participating centre

Wythenshawe Hospital

South Manchester

United Kingdom

M239LT

Sponsor information

Organisation

University Hospital of South Manchester NHS Foundation Trust (UK)

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

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