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A feasibility study comparing current keyhole vein removal training with a structured training programme

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Registration date 25/02/2022	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 11/09/2024	**Condition category** Surgery	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol

Background and study aims

Coronary artery bypass graft surgery (CABG) is a commonly performed surgical procedure for coronary artery disease. Currently, 20,000 bypass surgeries are carried out each year in the UK involving 290 surgical nurse practitioners and many more surgical trainee doctors who perform vein harvesting. A blood vessel (vein) from the leg is removed and used to bypass the blocked coronary arteries. The new vein takes over the job of supplying blood to the heart muscles and patients need to live with their vein graft for many years (typically 10 to 15 years). If the vein is mishandled or damaged during removal, it can become blocked. This can affect the patient's quality of life and cause repeated chest pain. Harvesting veins using keyhole surgery has been shown to reduce wound complications and improve patient satisfaction compared to traditional open vein harvesting. The current training for keyhole vein removal in cardiac surgery typically involves a limited number of practice sessions on a leg model and 1 week's training in the operating room, provided by a commercial trainer. However, a structured training programme is required for this procedure to improve vein quality and minimise problems for patients. Currently during training patients are used as "guinea pigs" by trainees. A recent survey of 151 healthcare professionals in 15 European countries found that 99% of specialists would like to have a structured keyhole training programme.

The study main investigator previously developed the Manchester Endoscopic Learning Tool (MELT), a structured training programme that consists of four sections (introducing the trainees to the theory, surgical video, gradual introduction to clinical practice and vein harvesting), with a minimum pass mark of 80% for each section. The first two phases of the MELT are skill-based e-learning and the second two phases are learning in clinical settings with patients.

The main aim of this study is to find out whether the structured comprehensive keyhole removal training programme will improve the quality of vein tube by improving the operator's skills and confidence.

Who can participate?

1. Qualified surgical care practitioners or trainees who are learning keyhole vein removal methods as part of their job
2. Patients aged over 18 years who are undergoing coronary artery bypass grafting surgery with

at least one length of vein which will be removed using keyhole method as part of their surgical procedure

What does the study involve?
Trainees are randomly allocated to one of two groups. Full training will be provided by the chief investigator for one group and the other group will be taught by the current company trainer. Various questionnaires need to be completed at different stages of the training and after training of the keyhole vein removal method. Trainees will be asked to provide 1cm x 3 vein pieces from the vein removed for surgery.
As part of their standard care, patients will be admitted to hospital for their heart bypass surgery (CABG). During the operation leg veins will be taken out for bypassing the blocked arteries in the heart, which is a routine procedure during bypass surgery. The hospital will have been randomly allocated for one of the two methods of training for vein removal and the removed vein will be used for CABG with a small sample of this vein will be taken to laboratory for further cell studies. The hospital may receive current standard training from the keyhole method company or structured training method.
One of the trainees will remove the leg vein and the researchers will follow up the patients' aftercare progress through their medical notes, a series of questionnaires over the telephone and a CT coronary angiogram between 6 to 9 months later. The samples taken from the vein (1 cm) will be taken to the laboratory. The researchers will look at how cells that make up the vein have reacted to the different vein removal techniques. All the samples will be coded with a unique reference number that will not include any personal data. Patients will be telephone interviewed by one of the researchers from their hospital after 1, 3, 6, 9, and 12 months using a standard questionnaire regarding their progress after the operation.

What are the possible benefits and risks of participating?
There will be no benefits directly for patients but the researchers can decide whether to provide structured training programme for healthcare professionals to provide good quality vein for bypass surgery. It may benefit future coronary artery bypass surgery patients if the structured training programme is better than current training programme.
Various studies show that the keyhole method has less chance (2% to 4%) of wound infection, problems with the wound closing, and serious discharge, pain and bruising. Some of the possible associated side effects are bruising of the vein and less carbon dioxide in the tunnel.
Patients will have one CT coronary angiogram which will be extra to those that they would have if they did not take part. The coronary CT scan uses ionising radiation to form images of the body and provide the doctor with other clinical information. Ionising radiation may cause cancer many years or decades after exposure. We are all at risk of developing cancer during our lifetime. 50% of the population is likely to develop one of the many forms of cancer at some stage during our lifetime. Taking part in this study may increase the chances of this happening to you by about 0.06%.

Where is the study run from?
Wythenshawe Hospital (UK)

When is the study starting and how long is it expected to run for?
August 2021 to September 2024

Who is funding this study?
National Institute of Health Research (NIHR) (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
310749

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
IRAS 310749, CPMS 51627

Study information

Scientific Title
A Cluster Randomised feasibility study comparing current Endoscopic (keyhole) vein harvesting training with Structured Training: the CREST trial

Acronym
CREST

Study objectives
Structured endoscopic vein harvesting training provides better quality veins than the current endoscopic vein harvesting training method.

Research questions:
1. Are there any differences in vein quality (histological level) and clinical outcomes between the two training groups?
2. Are there any differences in practitioner anxiety levels and operator skills and confidence?
3. Are there any differences in cost-effectiveness?
4. Are there any differences in patient-reported outcomes (i.e. health-related quality of life and patient satisfaction)?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 24/01/2022, Greater Manchester Central REC (Currently held by video-conference via Zoom; +44 (0)207 104 8133, +44 (0)207 104 8007, +44 (0)207 104 8208; gmcentral.rec@hra.nhs.uk), REC ref: 21/NW/0250

Study design
Cluster-randomized pilot trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Coronary artery bypass grafting surgery: endoscopic vein harvesting

Interventions
Hospitals will be randomised to use either the current keyhole training method or a structured keyhole training method using a cluster randomisation method (1:1 ratio of hospitals).

Current keyhole training method:
A thin camera is inserted through a small cut 2 -3 cm near the knee. The surgical team uses the camera to see the leg vein and to remove it with minimal damage to the muscles and tissues of the leg. This method will use a Getinge product which requires a CO_2 tunnel for vein dissection.

These trainees will be taught by the company surgical trainer using their training programme.

Intervention: Structured keyhole training method
A thin camera is inserted through a small cut 2-3 cm near the knee. The surgical team uses the camera to see the leg vein and to remove it with minimal damage to the muscles and tissues of the leg. This method will use a Getinge product which requires a CO_2 tunnel for vein dissection.

These trainees will be taught by a lead researcher Dr Krishnamoorthy using a structured step-by-step teaching method.

Carbon dioxide (CO_2) is used to open up the space and make the tunnel visible for harvesting the vein in both these systems. As a result, it is common for CO_2 bubbles to appear in the blood. Previous research suggests the actual risk of further complications occurring because of this is rare. The CO_2 bubbles will be monitored carefully by routine blood samples during the surgery to ensure that there is no harmful level in the blood.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Long saphenous vein integrity, as indicated by the level of histological damage on endothelial, muscular, and adventitial layer measured using the following assessment of histological vein samples collected on the day of surgery:
1.1. A 0-3 scale for circular and longitudinal muscle layer (where 0 is normal and 3 is severe damage)
1.2. A score of 0 to 100% for muscle detachment measured using a validated scoring system using for immunohistological staining
1.3. A 0-4 scale for endothelial damage where (where 0 is normal and 4 is a complete loss of endothelial layer)

Key secondary outcome(s))
1. Surgical Care Practitioner (SCP) anxiety levels measured using the Beck Anxiety Inventory scale, operator skills, and confidence during training and post-training
2. Patient satisfaction measured using a 100 mm visual analogue scale, with 100 mm indicating complete satisfaction of the leg wound before discharge from the hospital, and at 3 and 12 months
3. Post-surgical clinical outcomes including Major Adverse Cardiac Events (MACE): re-occurrence of angina, re-intervention, myocardial infarction, vein graft failure, stroke, and mortality measured using a telephone questionnaire at 1, 3, 6, 9, and 12 months
4. Wound assessment measured using vein scoring by consultant surgeons on the day of surgery
5. Wound complications measured using the Southampton modified asepsis score system until discharge and at 6 weeks
6. Cost-effectiveness analysis measured using the SF-36 and EQ-5D-5L quality of life questionnaires (incremental cost per QALY) pre-surgery, and at 3 and 12 months, and using telephone clinical MACE questionnaire to calculate the unit cost of all disposables and estate costs from admission until 12 months
7. Trainee satisfaction measured using the Learner Satisfaction Survey as part of Kirkpatrick learning tool (level 1 and 2) during training and post-training
8. Trainee technical skills measured using the Global Operative Assessment of Laparoscopic Skills (GOALS) scoring system during training and post-training

Completion date
31/03/2025

Eligibility

Key inclusion criteria
Trainees:
1. All qualified surgical care practitioners with at least 12 months of experience in open vein harvesting but no previous experience on EVH techniques will be eligible to participate. SCPs with experience in EVH procedures will be excluded.

2. SCPs in the intervention arm must own a smartphone because MELT training includes improvement of hand-eye coordination (full details given in recruitment justification) using phone games like Temple Run and Teeter, with a screen capture of daily scores logged centrally for analysis. The games were selected for their hand-eye coordination content as there are no specific smartphone games specifically for improving endoscopic vein harvesting techniques. Please note that these applications are free for any smartphone download and there is no need for any personally identifiable details to be entered unless the trainee wants to add their name to keep a track of their game progress.

Patients:
1. Patients aged over 18 years providing written informed consent to participate
2. Elective and urgent patients
3. Patients who need at least one length of long saphenous vein for surgery
4. Patients undergoing on-pump Coronary Artery Bypass Graft (CABG) surgery

Participant type(s)
Patient, Health professional

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
86

Key exclusion criteria
Trainees:
1. Under 12 months qualified
2. Do not want to participate in this study
3. SCPs with experience in EVH procedure
4. SCPs who do not have a smartphone and are not willing to use their phone to play games

Patients:
1. Patients undergoing emergency surgery
2. Patients undergoing off-pump CABG surgery
3. Contra-indication for endoscopic vein harvesting including varicosities of the long saphenous vein, small or thin legs (<7.5 cm diameter at the lower calf) or superficial Long Saphenous Vein (LSV) (less than 0.5 cm deep from the skin), determined using ultrasound scans
4. Patient with severe renal impairment

Date of first enrolment
01/03/2022

Date of final enrolment
31/05/2024

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Manchester Foundation Trust
Cardiothoracic Department
Southmoor Road
Manchester
United Kingdom
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Study participating centre
St James Cook Hospital
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Sponsor information

Organisation
Manchester University NHS Foundation Trust

ROR
https://ror.org/00he80998

Funder(s)

Funder type
Government

Funder Name

National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The study will have a huge raw dataset (multicentre) which will be difficult to upload on a public platform for access. The fully anonymous raw data will be available on request from the Manchester Foundation Trust as a (sponsorresearchsponsor@mft.nhs.uk) and from the chief investigator Dr Bhuvaneswari Krishnamoorthy (b.bibleraaj@salford.ac.uk). Please note that the anonymous data will not be available for anyone outside this study until the study is completed, analysed and published in a peer-reviewed scientific journal.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes