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The extent of intimal hyperplasia and atherogenesis in bypass vein grafts following different surgical preparation techniques

Submission date 02/03/2009	**Recruitment status** No longer recruiting	[X] Prospectively registered
		[_] Protocol
Registration date 30/04/2009	**Overall study status** Completed	[_] Statistical analysis plan
		[X] Results
Last Edited 11/02/2021	**Condition category** Circulatory System	[_] Individual participant data

Plain English summary of protocol

Background and study aims

The success of coronary bypass artery grafting surgery depends on the grafts created during the operation continuing to carry blood to the heart for many years. Most grafts are made from veins taken from the leg. Unfortunately, as many as 40% of all vein grafts become blocked within 12 years. When vein grafts become blocked, symptoms of angina may return and the risks of heart attack and death increase again. Therefore, it is important to discover new ways to prevent vein grafts from becoming blocked. Most studies in this field have investigated the ability of drugs to prevent blockages. The method of surgical preparation of the vein grafts at the time of the operation has not been studied in detail but may be an important factor causing vein grafts to become blocked. Currently, vein grafts are usually prepared by stripping away the surrounding fat at the time the vein is removed from the leg. The vein is then tested for leaks by filling the graft with fluid under high pressure, using a syringe. It is thought that this method may damage the vein. Other methods of preparation involve removing the vein from the leg with its surrounding fat and testing for leaks at lower pressure. The long-term benefits of these strategies are not known. The aim of this study is to test whether either of these methods is better than current practice.

Who can participate?

Patients aged 18 and older undergoing first-time elective coronary artery bypass graft at the Bristol Royal Infirmary having one or more saphenous (leg) vein grafts

What does the study involve?

Participants are randomly allocated to one of four treatments:

1. Removing the vein without the surrounding fat and testing for leaks at high pressure (current practice)
2. Removing the vein with the surrounding fat and testing at high pressure
3. Removing the vein without the surrounding fat and testing at low pressure
4. Removing the vein with the surrounding fat and testing at low pressure

Participants are followed up for one year, when they have detailed investigations of the internal diameter and the thickness of the wall of the vein grafts.

What are the possible benefits and risks of participating?
One or more of the methods being studied may reduce the chance of vein wall thickening and the graft itself becoming narrowed or blocked. This would lower their risk of suffering further heart complications in future. The information gained from this study will show the best way to prepare vein grafts in the future. However, it cannot be said for certain that any of the techniques will be better than the technique currently being used. The methods of graft preparation are perfectly safe and will not affect the success of the operation. In the previous study, combining removal of the vein with the surrounding fatty tissue and testing at normal blood pressure seemed to increase the risk of wound infection (from 5 to 10%) and numbness of the skin where the vein was taken from. However, these differences could also have happened by chance. Studying these possible side effects is one of key reasons for doing the research.
The angiogram is a procedure that the patient will have already received before their surgery, as part of their standard care to assess the disease in their coronary arteries. By participating in this study they will receive the procedure again, one year after surgery. The ultrasound test is done at the same time. The risks associated with the repeat angiogram will be the same and include possible bleeding or discomfort at the site of insertion of the catheter and a small risk (less than 1 in 1000) of heart attack, stroke or death. The angiogram also includes exposure to X-rays, which involves a small risk; the radiation dose is equivalent to about five years natural background radiation in the UK. During the angiogram they will be injected with a small amount of contrast material (a type of dye). In some rare cases people have an allergic reaction to this dye, but since they will have been injected with the same dye before the operation this is extremely unlikely. If they have a history of allergy to iodinated contrast material they must inform the doctor. The intravascular ultrasound procedure takes longer than a normal angiogram, about 30-40 minutes. The risk of complications is slightly higher because an extra procedure is involved. Nevertheless, intravascular ultrasound is a widely used method in research with patients who have heart disease.

Where is the study run from?
Bristol Royal Infirmary (UK)

When is the study starting and how long is it expected to run for?
August 2009 to July 2015

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Prof. Gianni Angelini
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Contact information

Type(s)
Scientific

Contact name
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Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CS/2009/3137

Study information

Scientific Title
A randomised controlled trial to assess the extent of intimal hyperplasia and atherogenesis in bypass vein grafts following different surgical preparation techniques

Acronym
HArVeST

Study objectives
The hypothesis is that saphenous vein graft patency is affected by the method of vein harvesting and preparation; it is believed that graft patency can be improved by retaining the pedicle of fat surrounding the vein when harvesting (rather than stripping it) and/or by flushing the vein at systemic pressure prior to grafting (rather than high pressure).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Wiltshire Research Ethics Committee, 14/05/2009, ref: 09/H0104/28

Study design
Single-centre four-group (factorial 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
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 disease

Interventions
All patients will receive saphenous vein grafts as part of their CABG procedure but the study will investigate the effects of different vein preparation techniques. The study is designed factorially with two factors of two levels: vein harvest technique (conventional versus pedicled) x vein distension pressure (conventional versus systemic)

As such there will be four different intervention groups:
CC: Conventional harvest (stripped vein) and conventional distension pressure (high)
PC: Pedicled harvest (vein with surrounding tissue) and conventional distension pressure (high)
CS: Conventional harvest (stripped vein) and and systemic distension pressure (low)
PS: Pedicled harvest (vein with surrounding tissue) and systemic distension pressure (low)

Intervention Type
Procedure/Surgery

Primary outcome measure
Wall thickness and lumen size measured with intravascular ultrasound (IVUS) at 12 months post-operatively, adjusting for baseline differences in wall thickness assessed by the histological analysis of harvested vein grafts at operation

Secondary outcome measures
1. Difference in lumen size and graft patency by quantitative angiography, between groups at 12 months post-operatively, adjusting for baseline differences in lumen size and wall thickness assessed by the histological analysis of harvested vein grafts at operation
2. Serious Adverse Events
3. Wound infection (ASEPSIS Score)
4. Length of stay
5. Neuropathic Pain Symptom Inventory (NPSI) leg wound pain or dysaesthesia at 3 and 12 months follow-up
6. Readmission rate within 12 months

Overall study start date
01/08/2009

Completion date
01/07/2015

Eligibility

Key inclusion criteria

Current inclusion criteria as of 08/11/2010:
Male and female patients (aged 18 years and older) undergoing first time elective (standard or urgent priority) coronary artery bypass graft (CABG) at the Bristol Royal Infirmary having one or more saphenous vein grafts will be invited to take part in the study.

Initial information at time of registration:
Male and female patients (aged 18 years and older) undergoing first time elective (standard or urgent priority) coronary artery bypass graft (CABG) at the Bristol Royal Infirmary having one or more vein grafts will be invited to take part in the study.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
96

Total final enrolment
96

Key exclusion criteria
Current exclusion criteria as of 30/08/2012:
1. Need for emergency CABG
2. Need for an additional procedure such as valve replacement
3. Ejection fraction less than 30%
4. Congestive cardiac failure
5. Peripheral vascular disease affecting the leg(s)
6. Pre-operative serum creatinine greater than 104 µmol/l
7. Allergy to iodinated contrast media
8. Unwillingness to participate in follow-up
9. Aged less than 18 years
10. Previous cardiac surgery

Previous exclusion criteria between 08/11/2010 and 30/08/2012:
6. Pre-operative serum creatinine greater than 120 µmol/l

Initial information at time of registration:
1. Need for emergency CABG
2. Need for an additional procedure such as valve replacement
3. Ejection fraction less than 35%
4. Congestive cardiac failure
5. Peripheral vascular disease
6. Pre-operative serum creatinine greater than 120 µmol/l

7. Allergy to iodinated contrast media
8. Unwillingness to participate in follow-up
9. Aged less than 18 years

Date of first enrolment
01/08/2009

Date of final enrolment
01/07/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Bristol Heart Institute
Bristol
United Kingdom
BS2 8HW

Sponsor information

Organisation
University Hospitals Bristol NHS Foundation Trust (UK)

Sponsor details
Research and Innovation Department
Education Centre, Level 3
Upper Maudlin Street
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Sponsor type
Hospital/treatment centre

Website
http://www.uhbristol.nhs.uk/

ROR
https://ror.org/04nm1cv11

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Biomedical Research Unit for Cardiovascular Disease

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

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?
Preprint results		16/01/2021		No	No