

A pilot study of stenting of autologous saphenous vein on early graft remodelling after coronary artery bypass surgery

Submission date 29/10/2001	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 29/10/2001	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 24/07/2012	Condition category Surgery	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
PG/96147

Study information

Scientific Title

Acronym

EXTENT-1

Study objectives

Brief summary:

Bypass grafting using leg veins is a very effective surgical treatment for advanced coronary heart disease, although the initial benefits of the operation tend to be lost over the following years. This is because the vein grafts themselves become blocked like the original coronary arteries. Many attempts have been made to prevent these late failures either by variations in surgical technique or by using drugs, however the problem remains. Based on a British Heart Foundation funded collaboration between basic scientists and cardiac surgeons stretching over the past 10 years, a radically new therapy has been devised. This involves wrapping the vein in a stocking-like material during the bypass operation so that it will be continuously supported during its life as a graft. In experimental studies, this has had a dramatic effect in reducing the thickening of the graft wall. The present project will be the first test of the effectiveness of the new technique in man.

Hypothesis:

Application of a highly porous non-restrictive external stent to autologous saphenous veins at the time of implantation of coronary artery bypass grafts will reduce graft thickening and neointima formation and increase lumen size.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Prevention of saphenous vein graft stenosis by the use of an external stent

Interventions

1. One group of patients will receive conventional bypass graft surgery with saphenous vein
2. In the second group the saphenous vein will be supported with a polyester made stent

Intervention Type

Procedure/Surgery

Phase

Not Specified

Primary outcome(s)

Study endpoints: Graft wall thickness and luminal size using intravascular ultrasound (IVUS) at time of operation and at follow-up. Wall and luminal volume will be computed from the 3-D reconstructions and compared to values obtained intraoperatively. Final wall and luminal volumes and the changes in these parameters will be compared in stented and unstented grafts. Angiography will be carried out as a necessary adjunct to intravascular ultrasound at follow-up.

Clinical Outcomes: Adverse clinical events, including death, myocardial infarction, bleeding, infections, need for reoperation, recurrence of symptoms will be recorded.

Key secondary outcome(s)

Not provided at time of registration

Completion date

30/03/2007

Eligibility

Key inclusion criteria

Patients undergoing coronary artery bypass surgery

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Not Specified

Key exclusion criteria

1. Re-do surgery
2. First CABG with an associated procedure
3. Associated valve disease
4. Recent MI (<1 month)
5. Poor ejection fraction (<30%)
6. Diabetes
7. Previous history of inflammatory disease
8. Unwillingness to participate in follow-up

Date of first enrolment

01/03/2005

Date of final enrolment

30/03/2007

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Department of Cardiac Surgery

Bristol

United Kingdom

BS2 8HW

Sponsor information

Organisation

British Heart Foundation (UK)

ROR

<https://ror.org/02wdwnk04>

Funder(s)

Funder type

Charity

Funder Name

British Heart Foundation (UK) (PG/96147)

Alternative Name(s)

The British Heart Foundation, the_bhf, BHF

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

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	01/08/2007		Yes	No