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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	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 29/10/2001	**Overall study status** Completed	
Last Edited 24/07/2012	**Condition category** Surgery	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study 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

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 measure
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.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/03/2005

Completion date
30/03/2007

Eligibility

Key inclusion criteria
Patients undergoing coronary artery bypass surgery

Participant type(s)
Patient

Age group
Adult

Sex
Not Specified

Target number of participants
40

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
England

United Kingdom

Study participating centre
Department of Cardiac Surgery
Bristol
United Kingdom
BS2 8HW

Sponsor information

Organisation
British Heart Foundation (UK)

Sponsor details
14 Fitzhardinge Street
London
United Kingdom
W1H 6DH
+44 (0)20 7935 0185
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Sponsor type
Charity

Website
http://www.bhf.org.uk/

ROR
https://ror.org/02wdwnk04

Funder(s)

Funder type
Charity

Funder Name
British Heart Foundation (UK) (PG/96147)

Alternative Name(s)
the_bhf, The British Heart Foundation, BHF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

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?
Results article	results	01/08/2007		Yes	No