

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

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

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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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

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**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\_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

## 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?
<a href="#"><u>Results article</u></a>	results	01/08/2007		Yes	No