# Leg closure study following saphenous vein harvesting for coronary artery bypass surgery

Submission date	Recruitment status	Prospectively registered
29/09/2006	Stopped	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
29/09/2006	Stopped	☐ Results
Last Edited	Condition category	☐ Individual participant data
28/09/2011	Surgery	☐ Record updated in last year

### Plain English summary of protocol

Not provided at time of registration

### Contact information

### Type(s)

Scientific

#### Contact name

Mr Michael Rosin

#### Contact details

Cardiothoracic Department
UHCW NHS Trust
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX
+44 02476 602020 ext 5540
mike.rosin@uhcw.nhs.uk

### Additional identifiers

Protocol serial number N0295165886

## Study information

Scientific Title

### **Study objectives**

Is using one layer closure (skin stitch only) as effective as two layer closure (fat and skin stitch) in closing a leg wound following saphenous vein removal, in relation to wound healing, infection and pain?

### 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)

**Not Specified** 

### Health condition(s) or problem(s) studied

Surgery: Saphenous vein harvesting

#### **Interventions**

One layer closure vs two layer closure

August 2008: trial stopped.

#### Intervention Type

Procedure/Surgery

### Phase

**Not Specified** 

### Primary outcome(s)

Determination of the best method of leg closure following vein harvesting for CABG

### Kev secondary outcome(s))

Not provided at time of registration

#### Completion date

22/10/2005

### **Eligibility**

### Key inclusion criteria

The study will include 100 consecutive patients. Patients undergoing coronary artery bypass grafting at Walsgrave Hospital under the care of Mr Rosin and Mr Norton (Consultant Cardiothoracic Surgeons). Inclusion criteria: patients who require vein harvesting from both legs allowing equal incisions.

### Participant type(s)

**Patient** 

### Healthy volunteers allowed

No

### Age group

Adult

#### Sex

**Not Specified** 

### Key exclusion criteria

- 1. Patients who do not wish to take part in the study
- 2. Have their vein harvested not using the open technique
- 3. Have their vein harvested by another operator
- 4. Harvest is abandoned because of technical difficulties
- 5. Have limb neuropathy
- 6. Have skin changes due to arterial, venous or nerve disease
- 7. Have leg ulcers
- 8. Have recent limb skin or tissue infection
- 9. Have varicosities along the long saphenous vein
- 10. Have had previous lower limb injuries

#### Date of first enrolment

23/03/2005

### Date of final enrolment

22/10/2005

### Locations

### Countries of recruitment

United Kingdom

England

# Study participating centre Cardiothoracic Department

Coventry United Kingdom CV2 2DX

### Sponsor information

### Organisation

Record Provided by the NHSTCT Register - 2006 Update - Department of Health

# Funder(s)

### Funder type

Government

### Funder Name

University Hospitals Coventry and Warwickshire NHS Trust (UK)

### **Results and Publications**

Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration