

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

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

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
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

Primary study design

Interventional

Study design

Randomised controlled trial

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

Key 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