

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

Submission date 29/09/2006	Recruitment status Stopped	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 29/09/2006	Overall study status Stopped	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 28/09/2011	Condition category Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

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 measure

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

Secondary outcome measures

Not provided at time of registration

Overall study start date

23/03/2005

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

Age group

Adult

Sex

Not Specified

Target number of participants

100

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

England

United Kingdom

Study participating centre
Cardiothoracic Department
Coventry
United Kingdom
CV2 2DX

Sponsor information

Organisation

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

Sponsor details

The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type

Government

Funder Name

University Hospitals Coventry and Warwickshire NHS Trust (UK)

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