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PIN (Perforate Invaginate) stripping of the long saphenous vein, in patients having varicose vein surgery, with or without groin dissection on the postoperative pain outcome: prospective, single blind, randomised controlled trial

Submission date 28/09/2007	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 28/09/2007	**Overall study status** Completed	
Last Edited 24/08/2015	**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
N0274181489

Study information

Scientific Title
PIN (Perforate Invaginate) stripping of the long saphenous vein, in patients having varicose vein surgery, with or without groin dissection on the postoperative pain outcome: prospective, single blind, randomised controlled trial

Study objectives
What are the outcomes of PIN (Perforate Invaginate) stripping of the long saphenous vein in patients having varicose vein surgery with or without groin dissection on postoperative 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)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Surgery: Long saphenous vein

Interventions
Patients were randomised to groin dissection (conventional practice) or no groin dissection (intervention group).

Intervention Type
Procedure/Surgery

Phase

Not Specified

Primary outcome measure
Numerical analogue pain score at 1, 6 and 12 hours post-op.

Secondary outcome measures
Analgesic requirements during first 24 hours post-op and first week post-op.

Overall study start date
15/04/2005

Completion date
31/03/2007

Eligibility

Key inclusion criteria
Patients with sapheno-femoral incompetence and long saphenous vein incompetence in thigh who are undergoing elective sapheno-femoral disconnection and PIN stripping of the long saphenous vein with multiple avulsions.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
25 in each group. 50 total.

Key exclusion criteria
Patients scheduled to undergo simultaneous saphenous vein surgery.

Date of first enrolment
15/04/2005

Date of final enrolment
31/03/2007

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
West Suffolk Hospitals NHS Trust
Bury St Edmunds
United Kingdom
IP33 2QZ

Sponsor information

Organisation
Record Provided by the NHSTCT Register - 2007 Update - Department of Health

Sponsor details
The Department of Health, Richmond House, 79 Whitehall
London
United Kingdom
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dhmail@doh.gsi.org.uk

Sponsor type
Government

Website
http://www.dh.gov.uk/Home/fs/en

Funder(s)

Funder type
Government

Funder Name
West Suffolk Hospitals NHS Trust (UK), NHS R&D support funding

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