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The value of local infiltration of bupivicaine during Perforate Invaginate (PIN) stripping of the long saphenous vein: a randomised, double-blind, placebo-controlled trial.

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/09/2004	**Overall study status** Completed	
Last Edited 02/07/2009	**Condition category** Signs and Symptoms	

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
N0274135608

Study information

Scientific Title

Study objectives
To determine whether infiltration of the strip tract with local anaesthetic during Perforate Invaginate (PIN) stripping produces a significant reduction in post-operative pain

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised double-blind placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Signs and Symptoms: Post-operative pain

Interventions
Infiltration of bupivicaine vs placebo

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
bupivicaine

Primary outcome measure

Numerical pain scores at 1, 6 and 24 hours post-operatively. Analgesic consumption in the first 24 hours post-operatively.

Secondary outcome measures
Not provided at time of registration

Overall study start date
04/07/2003

Completion date
31/03/2005

Eligibility

Key inclusion criteria
Patients with sapheno-femoral incompetence documented on duplex scanning who are undergoing elective unilateral 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
Added as of 15/04/2008: 27

Key exclusion criteria
Not provided at time of registration

Date of first enrolment
04/07/2003

Date of final enrolment
31/03/2005

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
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

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)

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/12/2007		Yes	No