ISRCTN58431114 https://doi.org/10.1186/ISRCTN58431114

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

Registration date
30/09/2004

Overall study status
Completed

Last Edited
02/07/2009

Condition category
Signs and Symptoms

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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

Key secondary outcome(s))
Not provided at time of registration

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

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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
United Kingdom

England

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

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type

Government

Funder Name
West Suffolk Hospitals NHS Trust (UK)

Results and Publications

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