ISRCTN77640412 https://doi.org/10.1186/ISRCTN77640412

A prospective randomised trial of local anaesthetic (LA) with adrenaline on varicose vein surgery

Submission date 30/09/2004	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 30/09/2004	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 06/11/2014	**Condition category** Circulatory System	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr Nick Hickey

Contact details
Worcestershire Royal Hospital
Charles Hastings Way
Worcester
United Kingdom
WR5 1DD

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N0282126753

Study information

Scientific Title

Study objectives
To assess the effect of preoperative subcutaneous administration of local anaesthetic (LA) with adrenaline into proposed groin and avulsion sites in limbs of patients undergoing varicose vein surgery.

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

Health condition(s) or problem(s) studied
Varicose veins

Interventions
Participants are randomised to preoperative subcutaneous administration of local anaesthetic with adrenaline into proposed groin and avulsion sites. Analysed using Mann-Whitney U test.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Adrenaline, local anaesthetic

Primary outcome measure

1. The number of phlebectomies performed, length of procedure and intra-operative blood loss recorded for each leg
2. Bruising above/below knee measured at 1 week post-operatively, cosmetic appearance graded and repeated at 6 weeks

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/10/2000

Completion date
01/09/2004

Eligibility

Key inclusion criteria
20 - 25 consecutive patients.

Participant type(s)
Patient

Age group
Not Specified

Sex
Not Specified

Target number of participants
25

Key exclusion criteria
1. Known adverse reaction to LA and/or adrenaline
2. Failure to give informed consent

Date of first enrolment
01/10/2000

Date of final enrolment
01/09/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Worcestershire Royal Hospital
Worcester
United Kingdom
WR5 1DD

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
Worcestershire Acute 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