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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 [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 30/09/2004	**Overall study status** Completed	
Last Edited 06/11/2014	**Condition category** Circulatory System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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

Study type(s)
Treatment

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(s)
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

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

Completion date
01/09/2004

Eligibility

Key inclusion criteria

20 - 25 consecutive patients.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Not Specified

Sex
Not Specified

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
United Kingdom

England

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

Sponsor information

Organisation
Department of Health

Funder(s)

Funder type
Government

Funder Name
Worcestershire Acute Hospitals NHS Trust (UK)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration