

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

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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

Primary study design

Interventional

Study design

Randomised controlled trial

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