

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

<b>Submission date</b> 30/09/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 30/09/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 06/11/2014	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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