# A randomised controlled trial investigating the role of subfascial endoscopic perforator vein surgery (SEPS) in the prevention of recurrence in primary long saphenous varicose veins

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
12/09/2003		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
12/09/2003	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
21/10/2010	Circulatory System			

#### Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

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# Additional identifiers

**EudraCT/CTIS** number

IRAS number

ClinicalTrials.gov number

#### Secondary identifying numbers

N0211091334

# Study information

#### Scientific Title

#### **Study objectives**

To investigate the fate of incompetent perforating veins (IPVs) following saphenofemoral ligation and stripping of the great saphenous vein (GSV), with or without subfascial endoscopic perforator surgery (SEPS)

#### 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

Cardiovascular: Primary long saphenous varicose veins

#### Interventions

Randomised controlled trial randomised into two groups:

Group 1 - subfascial endoscopic perforator vein surgery (SEPS)

Group 2 - standard open procedure

#### Intervention Type

Other

#### **Phase**

**Not Specified** 

#### Primary outcome measure

- 1. Improvement in function measured by refill time,
- 2. Incidence of recurrent reflux
- 3. Clinical recurrence
- 4. Cosmetic results

#### Secondary outcome measures

Not provided at time of registration

#### Overall study start date

01/09/2000

#### Completion date

31/12/2004

# **Eligibility**

#### Key inclusion criteria

- 1. Venous reflux (greater than 0.5 s) of the greater saphenous vein (GSV)
- 2. Additional incompetent perforating veins (IPVs)

#### Participant type(s)

**Patient** 

#### Age group

Adult

#### Sex

Both

#### Target number of participants

72

#### Key exclusion criteria

- 1. Ulceration,
- 2. Recurrent veins
- 3. Deep venous reflux/thrombosis
- 4. Saphenopopliteal reflux

#### Date of first enrolment

01/09/2000

#### Date of final enrolment

31/12/2004

# Locations

#### Countries of recruitment

England

#### **United Kingdom**

Study participating centre
The Whiteley Clinic
Guildford, Surrey
United Kingdom
GU2 7RF

# Sponsor information

#### Organisation

Department of Health (UK)

#### Sponsor details

Richmond House 79 Whitehall London United Kingdom SW1A 2NL

#### Sponsor type

Government

#### Website

http://www.doh.gov.uk

# Funder(s)

#### Funder type

Government

#### Funder Name

Royal Surrey County Hospital NHS Trust (UK) - NHS R&D funding

# **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

# Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2007		Yes	No