

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 12/09/2003	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 12/09/2003	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 21/10/2010	Condition category Circulatory System	☐ Individual participant data

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
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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**

United Kingdom

England

Study participating centre

The Whiteley Clinic

Guildford, Surrey

United Kingdom

GU2 7RF

Sponsor information**Organisation**

Department of Health (UK)

Funder(s)

Funder type

Government

Funder Name

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

Results and Publications

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