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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

Registration date
12/09/2003

Overall study status
Completed

Last Edited
21/10/2010

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr Mark Whiteley

Contact details
The Whiteley Clinic
1 Stirling House
Stirling Road
Guildford, Surrey
United Kingdom
GU2 7RF
+44 (0)1483 477180
info@thewhiteleyclinic.co.uk

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