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Endovascular Varicose vein Vnus® (endovenous radiofrequency ablation) vs Evlt (endovenous laser therapy) Randomised controlled Trial - EVVERT

Submission date
15/10/2008

Recruitment status
No longer recruiting

Registration date
30/01/2009

Overall study status
Completed

Last Edited
18/01/2012

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

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Additional identifiers

Protocol serial number
08/H0803/162

Study information

Scientific Title
A double-blind randomised controlled trial of radiofrequency versus laser treatment of great saphenous varicose veins

Acronym
EVVERT

Study objectives
Null hypothesis: There is no difference in outcome between patients having their great saphenous varicose veins treated with endovascular radiofrequency (VNUS®) or endovenous laser therapy (EVLT)

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study was approved by St George's, University of London (REC reference: 08/H0803/162; R&D reference: 08.0112).

Primary study design
Interventional

Study design
Double-blind randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Symptomatic great saphenous varicose veins

Interventions
Endovenous laser therapy (EVLT) vs endovenous radiofrequency ablation (VNUS Closure®).

Total duration of follow-up: 3 months

Intervention Type
Other

Phase
Not Specified

Primary outcome(s)
1. Patency of great saphenous vein as measured by duplex scanning. This will be measured pre-operatively, at one week and three months post-operatively.

2. Health questionnaires, recorded pre-operatively and 3 months post-operatively.
2.1. Specific: Aberdeen Varicose Vein Symptom Severity score (AVVSS)
2.2. Generic: Euroqol EQ-5D

Key secondary outcome(s)
1. Pain
1.1. Analogue pain score diary over first week
1.2. Record of analgesia taken. Duration of follow-up: 1 week

2. Bruising. Photographs of legs taken pre-operatively and 1 week post-operatively to assess degree of bruising.

Completion date
01/04/2009

Eligibility

Key inclusion criteria
1. Both males and females
2. Primary varicose veins
3. Symptomatic
4. Great saphenous territory

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Unable to give informed consent
2. Age <18 or >80
3. Recurrent varicosities
4. Pregnant
5. Short saphenous incompetence
6. Tortuous great saphenous vein - not amenable to endovascular treatment
7. Deep vein thrombosis or pulmonary embolism within last year
8. Deep venous insufficiency
9. Warfarinised patient
10. Non-steroidal allergy

Date of first enrolment
01/10/2008

Date of final enrolment
01/04/2009

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Department of Vascular Surgery
London
United Kingdom
SW17 0RE

Sponsor information

Organisation
St George's, University of London (UK)

ROR
https://ror.org/040f08y74

Funder(s)

Funder type
Charity

Funder Name
St George's, University of London Charitable Trust (UK)

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	01/12/2011		Yes	No