

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

<b>Submission date</b> 15/10/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/01/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 18/01/2012	<b>Condition category</b> Circulatory System	<input type="checkbox"/> 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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

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).

### **Study design**

Double-blind randomised controlled trial

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Not specified

### **Study type(s)**

Treatment

### **Participant information sheet**

Not available in web format, please contact Mr Ranjeet Brar (email: rbrar@sgul.ac.uk) to request a patient information sheet

### **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 measure**

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

## **Secondary outcome measures**

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.

## **Overall study start date**

01/10/2008

## **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

## **Age group**

Adult

## **Sex**

Both

## **Target number of participants**

**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**

England

United Kingdom

**Study participating centre****Department of Vascular Surgery**

London

United Kingdom

SW17 0RE

**Sponsor information****Organisation**

St George's, University of London (UK)

**Sponsor details**

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rbrar@sgul.ac.uk

**Sponsor type**  
University/education

**Website**  
<http://www.sgul.ac.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

**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?
<a href="#">Results article</a>	results	01/12/2011		Yes	No