

# Ultrasound guided foam sclerotherapy combined with sapheno-femoral ligation compared to surgical treatment of varicose veins

<b>Submission date</b> 15/12/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 20/04/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 22/03/2012	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<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

**Protocol serial number**  
G Geroulakos

## Study information

**Scientific Title**

Randomised controlled trial of ultrasound guided foam sclerotherapy combined with saphenofemoral ligation compared to surgical treatment of varicose veins

### **Study objectives**

The hypothesis of this study is that duplex guided foam sclerotherapy in combination with saphenofemoral ligation under local anaesthesia may save costs and treatment time and be more acceptable for patients than ligation and stripping of the greater saphenous vein and phlebectomies. This is because there is no need for general anaesthesia and it is a less invasive procedure.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

The Ealing and Mental Health Ethics Committee approved in 2003 (ref: LREC 03/04)

### **Study design**

Single centre randomised controlled parallel group trial

### **Primary study design**

Interventional

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

Treatment

### **Health condition(s) or problem(s) studied**

Chronic venous insufficiency

### **Interventions**

Group surgery:

1. High saphenofemoral ligation
2. Strip to the knee
3. Multiple phlebectomies

Group surgery and foam:

High saphenofemoral ligation under local anaesthesia and foam sclerotherapy under ultrasound guidance.

Both arms had 5 years treatment/ follow up (some patients up to a max of 7 years)

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome(s)**

1. Patient recovery period
2. Quality of life

Outcome measured up to 7 years maximum

**Key secondary outcome(s)**

1. Frequency of complications
2. Cost of the treatment

Outcome measured up to 7 years maximum

**Completion date**

01/02/2007

**Eligibility****Key inclusion criteria**

Primary symptomatic varicose veins involving the great saphenous system in patients whom had had no previous treatment for varicose veins and who were suitable for day case surgery

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

1. Primary varicosities involving the short saphenous vein
2. Patients with previous surgery or sclerotherapy for varicose veins
3. Previous deep vein thrombosis (DVT)
4. Risk factors for DVT
5. Coagulopathy
6. Peripheral vascular disease
7. Known allergy to anaesthetic or sclerosing agents
8. Previous iatrogenic allergic reaction
9. Malignancy
10. Pregnancy

**Date of first enrolment**

01/07/2003

**Date of final enrolment**

01/02/2007

**Locations****Countries of recruitment**

United Kingdom

England

### Study participating centre

**Ealing Hospital**  
Middlesex  
United Kingdom  
UB1 3HW

## Sponsor information

### Organisation

Ealing Hospital NHS Trust (UK)

### ROR

<https://ror.org/0380w8h49>

## Funder(s)

### Funder type

Industry

### Funder Name

STD Pharmaceuticals (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?
<a href="#">Results article</a>	results	01/02/2012		Yes	No