

# Performance of different stockings in the treatment of chronic venous insufficiency, post-thrombotic syndrome and lymphoedema compared to normal subjects

<b>Submission date</b> 28/12/2013	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 10/01/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 22/01/2019	<b>Condition category</b> Circulatory System	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Graduated elastic compression stockings are the universal treatment option for patients with varicose veins, pain and swelling after a blood clot in the vein and lymphoedema (swelling due to fluid accumulation). However, their effectiveness has never been fully studied. We want to compare the effectiveness of stockings of two different strengths. The results should be able to tell us which stocking is best and how much a stocking improves the blood circulation in veins compared to not wearing stockings.

### Who can participate?

Participants include normal volunteers without venous disease and patients with problems related to blood circulation in the veins.

### What does the study involve?

Participants will be asked to complete a short questionnaire. Participants are requested to lie on an examination couch with your leg exposed and your heel resting on a soft platform. A cuff, like that used for taking a blood pressure, will be placed around your thigh, squeezed and then released. The effect of this mild squeezing of your thigh will be measured using an inflatable air bag wrapped around your calf over the stocking. The calf bag will measure the change in the size of your calf whilst the thigh-cuff is inflated and deflated. This will be performed without a stocking and then with two stockings of different strengths.

### What are the possible benefits and risks of participating?

There will be no immediate direct benefit to those taking part. However, there should be benefits to future patients who require elastic stockings by customizing their strength based on their requirements. There are no risks to taking part in the study. The cuff used to compress the thigh uses less pressure than the cuff used for taking a blood pressure measurement. Care should be taken getting on and off the examination couch and help will be available, if required.

Where is the study run from?  
Josef Pflug Vascular Laboratory, Ealing Hospital (UK)

When is the study starting and how long is it expected to run for?  
February 2014 to February 2015

Who is funding the study?  
Bauerfeind AG (Germany)

Who is the main contact?  
Mr Christopher R Lattimer  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
Mr George Geroulakos

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**  
143608

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
IRAS project ID: 143608

## Study information

**Scientific Title**  
Outflow performance of different stockings in the treatment of chronic venous insufficiency, post-thrombotic syndrome and lymphoedema compared to normal subjects

**Study objectives**

Graduated elastic compression stockings improve the venous return compared to no stockings. Our hypothesis is that stronger stockings work better and there may be differences between the patient groups and normal subjects.

### **Ethics approval required**

Old ethics approval format

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

The NRES Committee London - Harrow, 10th December 2013, REC reference, 13/LO/1863. Final ethical opinion will be confirmed within a maximum of 60 days.

### **Study design**

Interventional, single centre study

### **Primary study design**

Interventional

### **Secondary study design**

Non randomised controlled trial

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

Hospital

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

Treatment

### **Participant information sheet**

Not available in web format, please use the contact details below to request a patient information sheet

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

Chronic venous or lymphatic disease

### **Interventions**

There will be 4 groups of participants, 12 in each group, making a total of 48:

- Group 1: Patients with primary varicose veins
- Group 2: Patients with the post-thrombotic syndrome
- Group 3: Patients with lymphoedema
- Group 4: Normal subjects

Each participant will receive 3 interventions applied in random order using sealed envelopes:

1. No intervention
2. Class 1 below-knee stocking (18-21 mmHg)
3. Class 2 below-knee stocking (23-32 mmHg)

These interventions will be tested using an inflatable thigh-cuff to restrict the venous return. The effects of this will be measured using air-plethysmography which records changes in calf volume. Stockings are expected to overcome the restriction of the thigh-cuff by preventing the calf from swelling, and also by a rapid decrease in calf volume on release of the thigh-cuff.

There is no follow-up as part of this study. Patients will have a NHS follow-up as part of their normal NHS care.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome measure**

Quantification of calf volume changes as a result of thigh-cuff inflations measured using air-plethysmography. The rate of change of calf volume and the amount of change will be measured at increasing thigh-cuff inflation pressures and after deflation. These outcomes will be measured during a single session lasting about 40 minutes.

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/02/2014

**Completion date**

31/01/2015

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

1. Untreated varicose veins, previous deep venous thrombosis (DVT), lymphoedema or normal controls
2. Leg symptoms (unless a control subject)
- 3.1 Great saphenous reflux > 0.5 sec
- 3.2. Reflux > 1 sec and/or obstruction in deep veins on duplex
- 3.3. Confirmation of lymphoedema by lymphoscintigraphy
4. Agile and able to get on and off an examination couch
5. Ability to comprehend study demands

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

48

**Key exclusion criteria**

1. Acute DVT within the last 3 months
2. Previous surgery/sclerotherapy for varicose veins
3. Venous ulceration over 2 cm in diameter
4. Gross pitting oedema of the ankle or calf
5. Pregnancy
6. Peripheral vascular disease [Ankle brachial pressure index (ABPI) < 0.9]
7. Cardiac failure
8. Breathlessness after mild exertion
9. Arthritis with significant impairment of mobility
10. Age less than 18 years

**Date of first enrolment**

01/02/2014

**Date of final enrolment**

31/01/2015

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre****Josef Pflug Vascular Laboratory**

Ealing Hospital

Uxbridge Road

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## **Sponsor information**

**Organisation**

Ealing Hospital NHS Trust (UK)

**Sponsor details**

Research and Development

Ealing Hospital

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**Sponsor type**

Hospital/treatment centre

**ROR**

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

## Funder(s)

**Funder type**

Industry

**Funder Name**

Bauerfeind AG (Germany)

## 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	01/07/2016	22/01/2019	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No