

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

Submission date 28/12/2013	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 10/01/2014	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 22/01/2019	Condition category Circulatory System	☐ 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

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Additional identifiers

Integrated Research Application System (IRAS)

143608

Protocol serial number

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

Study type(s)

Treatment

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(s)

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.

Key secondary outcome(s))

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

England

Study participating centre

Josef Pflug Vascular Laboratory

Ealing Hospital

Uxbridge Road

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Sponsor information

Organisation

Ealing Hospital NHS Trust (UK)

ROR

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

Funder(s)

Funder type

Industry

Funder Name

Bauerfeind AG (Germany)

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	01/07/2016	22/01/2019	Yes	No
HRA research summary			28/06/2023	No	No