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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

Registration date
10/01/2014

Overall study status
Completed

Last Edited
22/01/2019

Condition category
Circulatory System

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
c.lattimer09@imperial.ac.uk

Contact information

Type(s)
Scientific

Contact name
Mr George Geroulakos

Contact details
Josef Pflug Vascular Laboratory
Ealing Hospital
Uxbridge Road
Middlesex
United Kingdom
UB1 3HW
020 8967 5000
g.geroulakos@imperial.ac.uk

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
Middlesex
United Kingdom
UB1 3HW

Sponsor information

Organisation
Ealing Hospital NHS Trust (UK)

Sponsor details
Research and Development
Ealing Hospital
Uxbridge Road
Middlesex
England
United Kingdom
UB1 3HW

020 8967 5000
eht.researchdevelopmentmanager@nhs.net

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?
Results article	results	01/07/2016	22/01/2019	Yes	No
HRA research summary			28/06/2023	No	No