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Upward progressive versus degressive compressive stocking in patients with moderate to severe chronic venous insufficiency

Submission date
27/10/2011

Recruitment status
No longer recruiting

Registration date
03/01/2012

Overall study status
Completed

Last Edited
09/12/2015

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Chronic venous insufficiency is a medical condition where the veins cannot pump enough blood back to the heart. The disease mainly occurs in the legs and more commonly affects women. The symptoms of this disease include pain, swelling and redness of the legs. The main complications are ulcers and skin diseases. Treatment includes the wearing of special stockings which compress the legs. There are different types of stockings which exert different pressures on the legs. The aim of this study is to compare the effectiveness and tolerability of two types of stockings, one where the pressure increases from the ankle to the knee (progressive), and one where the pressure decreases from the ankle to the knee (degressive).

Who can participate?
Adult patients with moderate chronic venous insufficiency.

What does the study involve?
Participants are randomly allocated to wear one of the two types of stocking.

What are the possible benefits and risks of participating?
Should the new progressive type of stocking be more effective and/or better tolerated than the degressive stockings, patients in this group will have a better treatment. In the degressive group there will be no disadvantage since the patients will receive the usual treatment. In addition, as in any study the patients will be followed up more closely and the stockings will be given for free. There could be local discomfort such as constriction and skin irritation in both groups.

Where is the study run from?
Pierre Fabre Laboratories (France).

When is the study starting and how long is it expected to run for?
June 2007 to September 2008.

Who is funding the study?
Pierre Fabre Laboratories (France).

Who is the main contact?
Dr Serge Couzan

Contact information

Type(s)
Scientific

Contact name
Dr Serge Couzan

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104 rue Bergson
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
V00322 BC 401

Study information

Scientific Title
A randomised double-blind trial of upward progressive versus degressive compressive stocking in patients with moderate to severe chronic venous insufficiency

Study objectives
There is a higher impact on clinical symptoms in patients suffering moderate to severe chronic venous disease

Ethics approval required
Old ethics approval format

Ethics approval(s)
Committee to Protect People "Southeast I", University Hospital of Saint-Etienne [Comité de Protection des Personnes "Sud-Est I", Centre Hospitalier Universitaire de Saint-Etienne], 12/03/2007, ref: 2007-11 JV 2007/97

Study design

Multicentre randomised double-blind parallel-group study

Primary study design
Interventional

Secondary study design
Randomised parallel 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 desease (or insufficiency)

Interventions
Group Progressive NS : progressive compressive stockings (10 mmHg at ankle, 23 mmHg at upper calf)

For each of treatment arms the method and frequency of administration, and the total duration of treatment and follow-up products wear every day (weak-up to sleep) during 6 months

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Evaluation after three months of treatment - improvement of pain or heavy legs, without onset of either ulcer, deep or superficial vein thrombosis of the lower limb, or pulmonary embolism.

Secondary outcome measures
1. Compliance
2. Easiness of use
3. Discomfort/harm related to the compressive stockings at months one, three and six
4. Improvement or worsening of pain or heavy legs was evaluated using four-level Likert scales
5. Interviews concerning intercurrent venous or adverse events, compliance, easiness to apply, and discomfort/harm related to the stockings.
6. At month three, a physical examination was performed and CEAP and modified Venous Clinical Severity Score (VCSS) were evaluated

Overall study start date
27/06/2007

Completion date
25/09/2008

Eligibility

Key inclusion criteria
1. Male or female adult outpatients
2. Presenting current pain and/or heavy legs due to moderate to severe chronic venous insufficiency (CEAP C2b to C5)
3. Eligible for a 30 mmHg compressive therapy

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
400

Key exclusion criteria
1. Bandage therapy recommended
2. Current use of a compressive stocking >30 mmHg
3. Active ulcer
4. Deep vein thrombosis or pulmonary embolism in the past three months
5. Arterial disease of the lower limb
6. Non-venous oedema
7. Inflammatory, dermatologic or traumatic disorder of a lower limb
8. Known hypersensitivity to components of the study compressive stockings
9. Surgery or vascular procedure in the past month or planned in the next three months
10. Poor life expectancy
11. Inability to walk
12. Pregnancy

Date of first enrolment
27/06/2007

Date of final enrolment
25/09/2008

Locations

Countries of recruitment
France

Study participating centre
104 rue Bergson
Saint Etienne
France
42000

Sponsor information

Organisation
Pierre Fabre (France)

Sponsor details
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81106

Sponsor type
Industry

Website
http://www.pierre-fabre.com/

ROR
https://ror.org/04hdhz511

Funder(s)

Funder type
Industry

Funder Name
Pierre Fabre Laboratories (France)

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	01/11/2012		Yes	No