

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 03/01/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 09/12/2015	Condition category Circulatory System	<input type="checkbox"/> 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

Contact details
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Saint Etienne
France
42000

Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Chronic venous disease (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 (week-up to sleep) during 6 months

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

ROR

<https://ror.org/04hdhz511>

Funder(s)

Funder type

Industry

Funder Name

Pierre Fabre Laboratories (France)

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	01/11/2012		Yes	No