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Comparing two compression stockings in people with oedema (swelling caused by fluid collection) in the legs

Submission date
19/12/2019

Recruitment status
No longer recruiting

Registration date
24/01/2020

Overall study status
Completed

Last Edited
12/09/2023

Condition category
Circulatory System

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

Plain English summary of protocol

Background and study aims
Venous insufficiency, which is where the veins are not working effectively to return blood to the heart, and disorders of the lymphatic system, which circulates a fluid called lymph in the body, can result in oedema (swelling caused by fluid build-up). The usual treatment for oedema of the legs is compression therapy to force the fluid back into the circulatory system. Compression stockings can prevent and treat symptoms related to oedema of the legs. However, the effect of the compression stocking is only achieved with frequent use. Some people find compression stockings uncomfortable and difficult to put on. Research has shown that more than half of patients do not use compression stockings frequently enough.
Compression stockings are available in four different compression classes, which indicate different levels of compression pressure. The treatment is effective if the right pressure is maintained. However, studies have shown that Class 2 stockings, which are most commonly used, lose pressure while being worn.
The company PressCise has developed a stocking called Lundatex® stocking to be easy to put on and take off while maintaining its pressure. This study aims to compare Lundatex® stocking with another compression stocking that is already widely used.

Who can participate?
Adults aged 18 years or over with oedema in the leg(s) due to venous insufficiency or lymphatic disease

What does the study involve?
Participants will be randomly allocated to one of two groups: the intervention group or the control group. Participants in the intervention group will receive the Lundatex® stocking Class 2) and the participants in the control group will receive the Actico® UlcerSys stocking kit (Class 3, meaning it provides more pressure than a Class 2 stocking). The participants are instructed to use the compression stocking for 2 weeks.
The study includes two visits to the clinic. At the first visit, the participant fills in a questionnaire regarding background information and their previous experience of compression stockings. The leg circumferences will be measured with a measuring tape and the compression pressure under

the stocking will be measured with two sensors. The participant will be instructed in how to take on and off the stocking. At the second visit, after 2 weeks, the participant fills in a second questionnaire regarding experiences of the current stocking and same measurements of leg circumferences and compression pressure will take place. Thereafter, the participation is ended and the participant is allowed to keep the compression stocking for free.

What are the possible benefits and risks of participating?
Treatment with the compression stockings can cause side effects such as tingling and numbness in the toes due to compression and skin redness and/or itching due to hypersensitivity or allergy to the stocking materials. If these, or other unexpected side effects occur, treatment will be stopped. However, these side effects are considered minor and no more serious medical risk is considered to exist. Side effects will be recorded in an adverse event report.

Where is the study run from?
South Älvsborg Hospital (Sweden)

Who is funding the study?
VINNOVA (Sweden) and Research Council South Älvsborg (Sweden)

When is the study starting and how long is it expected to run for?
January 2018 to February 2021

Who is the main contact?
Ulrika Källman, ulrika.kallman@vgregion.se

Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title

Compression from a patient perspective - evaluation of a new innovative compression stocking with well defined pressure, in a randomized controlled trial

Study objectives
The purpose of the study is to evaluate the Lundatex® Class 2 compression stocking with regard to oedema reduction in relation to the patient's compliance with treatment, and in relation to treatment with the Compression stocking Actico® UlcerSys.

Research questions:
1. Does treatment with Lundatex® Class 2 compression stocking lead to reduced oedema, equivalent or more, in relation to treatment with Actico® UlcerSys?
2. Does treatment with Lundatex® Class 2 compression stocking lead to equivalent or better compliance than regular compression therapy with Actico® UlcerSys?
3. Does the patient consider the Lundatex® stocking to be equivalent or more comfortable to wear, easier to put on and off, and provide better symptom relief than Actico® UlcerSys?
4. Do Lundatex® and Actico® UlcerSys stockings lose some compression pressure after 2 weeks of use?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/11/2018, Gothenburg County Council Ethics Board (Box 401, 405 30 Göteborg , Sweden; +46 031-786 68 21; registrator@etikprovning.se), ref: Dnr 956-18, T1126-18

Study design
Two-arm prospective randomized non-blinded pilot study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic venous insufficiency (CVI), deep vein thrombosis, lymphedema

Interventions
Intervention: Lundatex® stocking – knee-high compression stocking Class 2 (23-32 mmHg). The stocking is used during the daytime for 2 weeks.

Control: Actico® UlcerSys – knee-high compression stocking kit, Class 3 (33-44 mmHg). Time: The inner stocking is used day and night and the outer stocking in the daytime only. The stockings are used together for 2 weeks.

The participants are randomized to each group: 10 participants to the intervention group and 10 to the control group. Randomization is done using a random formula in Excel.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
1. Lundatex® 2. Actico® UlcerSys

Primary outcome(s)
Degree of oedema assessed by measuring the circumference of the lower leg will be measured every 4 cm, with start at a predetermined and well-defined zero point with a specially designed tape measure (Perikit) at baseline and at the end of the 2-week treatment period

Key secondary outcome(s))
1. Stocking compression pressure at baseline and after 2 weeks measured using two pressure sensors (Picopress®, Microlab, Italy) placed on two defined sites - just above the ankle and above the place where the calf has its largest circumference
2. Participant’s compliance assessed at the end of the 2-week treatment period by asking them how many days they used the stockings
3. Participant’s perceptions of the compression stocking's comfort assessed using a 1-10 scale at the end of the 2-week treatment period
4. Participant’s perceptions of the compression stocking's usefulness assessed using a 1-10 scale at the end of the 2-week treatment period
5. Participant’s perceptions of symptom relief provided by the compression stocking assessed using a 1-10 scale at the end of the 2-week treatment period

Completion date
21/02/2021

Eligibility

Key inclusion criteria
1. Venous insufficiency of the lower leg and classified as C3-C6 according to the Clinical-Aetiology-Anatomic-Pathophysiologic (CEAP) system or lymphedema
2. Leg circumference between 20 cm and 65 cm at the narrowest and widest places
3. Can tolerate compression therapy
4. Ankle-brachial pressure index (ABPI) >0.8
5. Has given consent to participate in the study
6. Needs compression treatment class 2 or class 3 (23-32 mmHg and 34-46 mmHg, respectively according to the RAL-GZG/ENV standard)
7. Aged 18 years or above

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit

18 years

Sex
All

Total final enrolment
25

Key exclusion criteria
1. Venous insufficiency classified C1 and C2 according to the Clinical-Aetiology-Anatomic-Pathophysiologic (CEAP) system
2. Arterial insufficiency
3. Ankle-brachial pressure index (ABPI) <0.8
4. Leg circumference less than 20 cm or greater than 65 cm
5. Poor or no tolerance of compression
6. Lipoedema
7. Diabetes
8. Heart failure
9. Other conditions that, in the examiner's opinion, restrict the patient from participating in the study

Date of first enrolment
01/10/2019

Date of final enrolment
02/02/2021

Locations

Countries of recruitment
Sweden

Study participating centre
South Älvsborg Hospital
Dermatology Department
Brämhultsvägen 53
Boås
Sweden
50457

Sponsor information

Organisation
PressCise (Sweden)

ROR
https://ror.org/03w1yvq02

Funder(s)

Funder type
Government

Funder Name
VINNOVA

Alternative Name(s)
Swedish Governmental Agency for Innovation Systems, Vinnovase

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Sweden

Funder Name
Research Council South Älvsborg

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the study will be available upon request from Ulrika Källman, ulrika.kallman@vgregion.se. Data will be available after accepted peer-reviewed publication.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		11/09/2023	12/09/2023	Yes	No