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A pilot study to observe the use of a portable Pneumatic compression pump as part of self-management in swollen legs

Submission date
07/03/2025

Recruitment status
Recruiting

Registration date
06/06/2025

Overall study status
Ongoing

Last Edited
06/06/2025

Condition category
Circulatory System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
The study aims to evaluate the use of the Haddenham Lymphflow Go device for managing lymphoedema or chronic venous insufficiency. This device helps reduce swelling in the limbs. It has been tested on healthy adults and is now being tested on people with these conditions to see if it is safe and effective.

Who can participate?
People can participate if they have a confirmed diagnosis of primary or secondary lymphoedema, oedema following trauma and/or sports injuries, post immobilization oedema, venous insufficiency, treatment and assistance in healing stasis dermatitis, venous stasis ulcers or arterial and diabetic ulcers, or phlebolymphoedema. They must also have the capacity to provide informed consent and follow instructions for using the device as stated in the instructions for use (IFU). Additionally, participants need to have good mobility, allowing them to lift their legs when sitting and safely position themselves on a treatment couch. Lastly, their BMI should be less than 32 kg/m².

What does the study involve?
Participants will attend an initial clinic appointment where they will read the Participant Information Sheet, sign a consent form, have their legs measured and photographed, complete a quality of life questionnaire, and use the device for one treatment cycle. They will then take the device home and use it daily for two weeks. After two weeks, they will return for a final appointment to repeat the measurements and return the device.

What are the possible benefits and risks of participating?
Potential benefits include improvement or maintenance of the condition. Risks include discomfort or pain from using the device, or device failure. Proper training and instructions will be provided to minimize these risks. If discomfort occurs, participants should stop using the device and contact the study team.

Where is the study run from?
The Lighter Touch, a private clinic in Malvern (UK)

When is the study starting and how long is it expected to run for?
November 2024 to September 2025

Who is funding the study?
Haddenham Healthcare Ltd. (UK)

Who is the main contact?
Natalie Phillips, MSc Lymphoedema RN, natalie@hadhealth.com

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
355616

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title

A pilot evaluation on the safety and efficacy of the Haddenham Lymphflow Go pneumatic compression device in patients with lymphoedema and chronic venous insufficiency as part of self management.

Study objectives
This small pilot study aims to demonstrate safety and efficacy of the Lymphflow Go in a small cohort of patients, with and emphasis placed on the portability and usability of the device and whether the device is a useful adjunct to self-care which in turn will reduce the burden of self-management on the patient as visits to the clinical settings can be reduced, furthermore research has shown a reduction in infections associated with lymphoedema, which in turn reduces the burden on the health service.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 14/05/2025, North of Scotland Research Ethics Committee 1 (Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE, United Kingdom; +44 1224558458; gram.nosres@nhs.scot), ref: 25/NS/0042

Study design
Research approach will utilise a mixed methods approach to collect data on both the effect of the intervention and the ease of use for the participant

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Other

Study type(s)
Safety, Efficacy

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Lymphoedema and chronic venous insufficiency

Interventions
Day 1- Initial Appointment
During the initial appointment (Day 1) participant will be asked to expose their legs for a series of measurements/procedures.
These measurements/procedures will consist of the following:
1. Limb volume measurements using a tape measure, to take circumference measurements of your legs at 4cm intervals, these will be documented on a spreadsheet which has formulas to calculate the overall limb volume measurements.

2. We will use a handheld device called a Lymph Scanner, which is a small probe placed onto the skin at several points to document overall tissue fluid content.
3. Photographs of the participants legs will be taken by digital camera and saved on an encrypted laptop. These will be of the limbs only, photographs of the face or any identifiers will not be obtained.
4. Participants will be asked to complete a quality of life questionnaire called LymQol.

Participants will be asked to confirm they are not pregnant, either by confirming medical history or by performing a pregnancy test. they will then be asked to read the instructions for use, apply the correctly sized device and complete one treatment cycle.
The participant will then be asked to take the device home with them.

Day 2 to Day 13- Home based Treatment
Use the device at home, every day for a period of 2 weeks.
They should continue with their normal self-management routine during this 2-week period. At the end of the home-based treatment period, they will return to the site.

Day 14- Final Appointment
The participant will return to the site for a final appointment (Day 14). During the visit, they will use the device for the final time and return the device to the investigators where measurements that were taken at the initial visit will be repeated.

Intervention Type
Device

Pharmaceutical study type(s)
Not Applicable

Phase
Phase II

Drug/device/biological/vaccine name(s)
Haddenham Lympflow Go pneumatic compression device

Primary outcome measure
1. Limb Volume measurements taken using a tape measure and inputted into LIMBSTAT at baseline and day 14
2. Percentage water content taken using the Delfin® Lymph Scanner® at set points throughout the limb taken at baseline and day 14

Secondary outcome measures
1. Quality of life questionnaire using LYMQOL taken at baseline and day 14
2. Feedback questionnaire to be completed at the end of the study on day 14

Overall study start date
01/11/2024

Completion date
16/09/2025

Eligibility

Key inclusion criteria
1. Confirmed diagnosis of Primary/Secondary Lymphoedema, Oedema following trauma and/or sports injuries, Post Immobilization Oedema, Venous Insufficiency, Treatment and Assistance in Healing Stasis Dermatitis, Venous, Stasis Ulcers or Arterial and Diabetic Ulcers, Phlebolymphoedema.
2. Have capacity to provide informed consent and follow instructions for using the device as stated in the instructions for use (IFU).
3. Have good mobility which allows to lift legs when sitting and safely position on a treatment couch.
4. BMI less than 32 kg/m².

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
90 Years

Sex
Both

Target number of participants
10

Key exclusion criteria
1. Aged under 18 years old.
2. Do not have capacity to provide informed consent or follow the instructions in the IFU.
3. Have limited mobility which means participants are unable to lift their legs or safely position themselves on a treatment couch.
4. BMI over 32 kg/m².
5. History or active cardiovascular diseases: Heart Failure, Acute Venous Disease, Severe Peripheral Artery Disease
6. Active Skin or Limb Infection/Inflammatory Disease
7. Any circumstance where increased lymphatic or venous return is undesirable.
8. Pregnancy

Date of first enrolment
02/06/2025

Date of final enrolment
02/09/2025

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
The Lighter Touch
64 Worcester Road
Great Malvern
United Kingdom
WR14 4AB

Sponsor information

Organisation
Louis Wakelin Haddenham Healthcare Ltd

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Sponsor type
Industry

Website
https://www.hadhealth.com

Funder(s)

Funder type
Industry

Funder Name
Haddenham Healthcare Ltd

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
10/05/2026

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study will be published as a supplement to the results publication

IPD sharing plan summary
Published as a supplement to the results publication