Graduated compression stockings for patients with a deep vein thrombosis to prevent long-term symptoms, known as post-thrombotic syndrome

Submission date 28/10/2019	Recruitment status Stopped	[X] Prospectively registered[X] Protocol
Registration date	Overall study status	Statistical analysis plan
30/10/2019	Stopped	☐ Results
Last Edited	Condition category	☐ Individual participant data
26/09/2022	Circulatory System	Record updated in last year

Plain English summary of protocol

Background and study aims

Patients with a deep vein thrombosis (DVT) may develop long-term symptoms, such as lifelong leg pain, skin changes and occasionally ulceration, known as post-thrombotic syndrome (PTS). This affects about half of people with a history of DVT. This study aims to show whether the regular use of a compression stocking after DVT in the leg, prevents long-term pain, swelling and ulceration. Currently small trials show varied results and a large trial is required to answer the question.

Who can participate?

Patients aged 18 and over at participating centres recently diagnosed with a deep vein thrombosis

What does the study involve?

Participants are randomly allocated to receive either blood-thinning medication, or blood-thinning medication and an additional compression stocking. This is a tight, custom-fitted stocking that they are asked to wear whilst they are awake as much as possible for between 6-30 months. Patients are aware of which group they are in, but are asked not to wear the stocking when they come for their assessment. This keeps the researchers impartial. To help participants remember to wear stockings they have access to an educational video, a Facebook support group and weekly SMS reminders. After the trial, patients do not need to wear their stockings. As some patients find putting on a stocking tricky, there are a variety of free aids to help people use them as well as training on how to put them on. In addition, there are cotton stockings to wear in the summer months, more elegant stockings that can be worn out for women, and stockings that resemble socks for men.

What are the possible benefits and risks of participating?

Those patients who receive a stocking may have a lower risk of long-term pain, swelling and ulceration. They will also have the benefit of peer support via an online anonymous group and

receive additional education about deep vein thrombosis. Those patients who are not asked to wear a stocking will still benefit from longer, enhanced follow up after deep vein thrombosis. Participants in both groups of the trial will be monitored closely for any complications of deep vein thrombosis, so that they can quickly be detected and acted upon. All patients will also have the arteries in their legs checked for adequate flow down to the feet.

Where is the study run from? Imperial College London (UK)

When is the study starting and how long is it expected to run for? May 2019 to December 2023

Who is funding the study? National Institute for Health Research (UK)

Who is the main contact? Rebecca Lawton chapstrial@imperial.ac.uk

Study website

https://www.imperial.ac.uk/department-surgery-cancer/research/surgery/clinical-trials/chapstrial/

Contact information

Type(s)

Scientific

Contact name

Miss Rebecca Lawton

Contact details

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

NCT04103112

Secondary identifying numbers

CPMS: 42347; HTA 17/147/47

Study information

Scientific Title

Compression hosiery to avoid post-thrombotic syndrome

Acronym

CHAPS; version 1.0

Study objectives

Every year 1 in 1000 persons in the UK are diagnosed with a blood clot in the leg veins (deep vein thrombosis). In just under half of those with deep vein thrombosis, leg pain, swelling and skin breakdown (ulcers) can occur, a lifelong condition called post-thrombotic syndrome. This impacts a person's ability to work, their confidence and independence. In most patients, there is no effective treatment and they lose income from unemployment. Ulcers, if they occur, require bandaging that needs to be changed twice weekly.

Treatment guidelines for deep vein thrombosis do not currently include the use of compression stockings. They can sometimes be difficult to put on for those who cannot bend down, the stockings can slip or roll down, or become uncomfortable in hot weather. Stockings cost the NHS approximately £50 every 6 months.

The evidence for stockings comes from two early trials comparing patients wearing a stocking to those who did not. There was a large benefit in both these trials for wearing a stocking, with no major side effects. In 2014, a Canadian group published a trial comparing wearing a compression stocking to wearing a non-compressive stocking. The rates of post-thrombotic syndrome were identical. The Canadian trial also suggested that only half of patients actually wear stockings, one reason the trial may have shown no difference. The Canadian trial suggested that stockings did not prevent future thrombosis or help leg pain. Whilst UK NICE recommendations are to avoid stockings after DVT, European recommendations are to still wear them. The contradictory results of these three trials have led us to design the CHAPS trial.

The aim of CHAPS is to confirm whether there is a real benefit of wearing stockings in addition to the standard treatment for deep vein thrombosis, which is blood-thinning medication.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 14/10/2019, London - Bloomsbury Research Ethics Committee (HRA RES Centre Manchester, Barlow House 3rd Floor, 4 Minshull Street, Manchester, M1 3DZ, UK; Tel: +44 (0) 2071048127; Email: nrescommittee.london-bloomsbury@nhs.net), ref: 19/LO/1585

Study design

Randomised; Interventional; Design type: Prevention, Device

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied

Post-thrombotic syndrome

Interventions

Participants are randomly allocated to receive either blood-thinning medication, or blood-thinning medication and an additional compression stocking. This is a tight, custom-fitted stocking that they are asked to wear whilst they are awake as much as possible for between 6-30 months. Patients are aware of which group they are in, but are asked not to wear the stocking when they come for their assessment. This keeps the researchers impartial. To help participants remember to wear stockings they have access to an educational video, a Facebook support group and weekly SMS reminders. After the trial, patients do not need to wear their stockings. As some patients find putting on a stocking tricky, there are a variety of free aids to help people use them as well as training on how to put them on. In addition, there are cotton stockings to wear in the summer months, more elegant stockings that can be worn out for women, and stockings that resemble socks for men.

Intervention Type

Mixed

Primary outcome measure

Incidence of Post Thrombotic Syndrome (PTS) using the validated Villalta criteria over a median 18-month follow-up

Secondary outcome measures

- 1. Venous ulceration incidence measured by the validated Villalta criteria over a median 18-month follow-up
- 2. Employment status (change in number of days working from baseline)
- 3. Disease-specific and generic quality of life measured using VEINES-QoL and EuroQoL EQ5D scales at baseline, 6 months, 12 months and end of study visit
- 4. Adherence to stockings and anticoagulants measured using patient self-report over a median 18-month follow-up
- 5. Cost-effectiveness of stocking prescription incremental cost-effectiveness ratio (ICER) from the EQ-5D questionnaire, with appropriate sensitivity analysis

Overall study start date

Completion date

31/12/2023

Reason abandoned (if study stopped)

Participant recruitment issue

Eligibility

Key inclusion criteria

- 1. Symptomatic presentation of first deep vein thrombosis, < 2 weeks from diagnosis
- 2. Imaging confirmed, lower limb deep vein thrombosis (popliteal, femoral, iliac or combination)
- 3. Ability to give informed consent
- 4. Age 18 or over

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 864; UK Sample Size: 864

Total final enrolment

152

Key exclusion criteria

Current participant exclusion criteria as of 21/12/2021:

- 1. Life expectancy < 2 years
- 2. Contraindication to wearing graduated compression stockings
- 3. Previously intolerant of or already wearing graduated compression stockings for more than 1 month
- 4. Ankle brachial pressure index (ABPI) < 0.8 or pedal pulses absent
- 5. Bilateral deep vein thrombosis
- 6. Previous chronic venous insufficiency (patients with existing chronic skin changes or ulceration, defined as C5 or C6 by CEAP classification)
- 7. Pre-existing post thrombotic syndrome, significant leg pain (e.g. knee arthritis, spinal claudication) or oedema (e.g. lymphoedema)
- 8. Newly diagnosed cancer, metastatic cancer, or cancer undergoing active treatment or palliation
- 9. Contraindication to anticoagulation
- 10. Known allergy to fabric in compression stockings

Previous participant exclusion criteria:

- 1. Life expectancy < 2 years
- 2. Contraindication to wearing graduated compression stockings
- 3. Previously intolerant of or already wearing graduated compression stockings for more than 1 month
- 4. Ankle brachial pressure index (ABPI) < 0.8 or pedal pulses absent
- 5. Bilateral deep vein thrombosis
- 6. Previous chronic venous insufficiency (patients with existing chronic skin changes or ulceration, defined as C4,5,6 by CEAP classification)
- 7. Pre-existing post thrombotic syndrome, significant leg pain (e.g. knee arthritis, spinal claudication) or oedema (e.g. lymphoedema)
- 8. Newly diagnosed cancer, metastatic cancer, or cancer undergoing active treatment or palliation
- 9. Contraindication to anticoagulation
- 10. Known allergy to fabric in compression stockings

Date of first enrolment

18/11/2019

Date of final enrolment

01/01/2023

Locations

Countries of recruitment

England

United Kingdom

Wales

Study participating centre Imperial College Healthcare NHS Trust

St. Marys Hospital Praed Street London United Kingdom W2 1NY

Study participating centre Guy's and St Thomas' NHS Foundation Trust

Trust Offices Guy's Hospital Great Maze Pond London United Kingdom SE1 9RT

Study participating centre King's College Hospital NHS Foundation Trust

Denmark Hill London United Kingdom SE5 9RS

Study participating centre

University Hospitals Birmingham NHS Foundation Trust

Trust HQ, PO Box 9551 Queen Elizabeth Medical Centre Edgbaston Birmingham United Kingdom B15 2TH

Study participating centre Royal Free London NHS Foundation Trust

Royal Free Hospital Pond Street London United Kingdom NW3 2QG

Study participating centre London North West University Healthcare NHS Trust

Northwick Park Hospital Watford Road Harrow United Kingdom HA1 3UJ

Study participating centre Hampshire Hospitals NHS Foundation Trust

Aldermaston Road Basingstoke United Kingdom RG24 9NA

Study participating centre Basildon and Thurrock University Hospitals NHS Foundation Trust

Basildon Hospital Nethermayne Basildon United Kingdom SS16 5NL

Study participating centre

The Newcastle Upon Tyne Hospitals NHS Foundation Trust

Freeman Hospital
Freeman Road
High Heaton
Newcastle-upon-Tyne
United Kingdom
NE7 7DN

Study participating centre East Cheshire NHS Trust,

Macclesfield District Hospital Victoria Road Macclesfield United Kingdom SK10 3BL

Study participating centre Salisbury NHS Foundation Trust

Haematology Department Salisbury District Hospital Odstock Road Salisbury United Kingdom SP2 8BJ

Study participating centre

Barking, Havering and Redbridge University Hospitals NHS Trust

Queens Hospital Rom Valley Way Romford United Kingdom RM7 0AG

Study participating centre Maidstone & Tunbridge Wells NHS Trust Hq

Maidstone Hospital Hermitage Lane Maidstone United Kingdom ME16 9QQ

Study participating centre

North Cumbria Integrated Care NHS Foundation Trust

Pillars Building Cumberland Infirmary Infirmary Street Carlisle United Kingdom CA2 7HY

Study participating centre Royal Hull Hospitals NHS Trust

Hull Royal Infirmary Anlaby Road Hull United Kingdom HU3 2JZ

Study participating centre

Countess of Chester Hospital NHS Foundation Trust

Countess of Chester Health Park Liverpool Road Chester United Kingdom CH2 1UL

Study participating centre

University Hospital Southampton NHS Foundation Trust

Cardiovascular and Thoracic Surgery E Level North Wing Southampton General Hospital Tremona Road Southampton United Kingdom SO16 6YD

Study participating centre Yeovil District Hospital NHS Foundation Trust

Higher Kingston Yeovil United Kingdom BA21 4AT

Study participating centre Royal Cornwall Hospitals NHS Trust

F50 The Knowledge Spa Treliske Truro United Kingdom TR1 3HD

Study participating centre Bolton NHS Foundation Trust

The Royal Bolton Hospital Minerva Road Farnworth Bolton United Kingdom BL4 0JR

Study participating centre Nottingham University Hospital NHS Trust

Queens Medical Centre Campus Haemostasis and Thrombosis department D Floor East Block Derby Road Nottingham United Kingdom NG7 2UH

Study participating centre Derby Teaching Hospitals NHS Foundation Trust

Royal Derby Hospital Uttoxeter Road Derby United Kingdom DE22 3NE

Study participating centre York Teaching Hospital NHS Foundation Trust

The York Hospital Wigginton Road York United Kingdom YO31 8HE

Study participating centre Betsi Cadwaladr University Health Board

DVT Office, Ground Floor Glan Clwyd Hospital Bodelwyddan Rhyl United Kingdom LL18 5UJ

Sponsor information

Organisation

Imperial College of Science, Technology and Medicine

Sponsor details

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+44 (0)207 594 9459
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Sponsor type

University/education

ROR

https://ror.org/041kmwe10

Funder(s)

Funder type

Government

Funder Name

Health Technology Assessment Programme

Alternative Name(s)

NIHR Health Technology Assessment Programme, HTA

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

Results and Publications

Publication and dissemination plan

Patients and relatives have been involved in the design of the research, drafting this summary and will sit on our trial committees. This will mean that patients have a voice during the running of the trial. For example, this allows the voice of participants to be heard on the trial steering committee. The researchers are working with the charity Thrombosis UK and the results of the trial will be made available on their website.

- 1. A protocol paper is currently being drafted and will be submitted to a medical journal
- 2. Peer-reviewed scientific journals
- 3. Conference presentation
- 4. Publication on website
- 5. Submission to regulatory authorities

Intention to publish date

31/12/2024

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type Details Date created Date added Peer reviewed? Patient-facing?

 Protocol article
 12/04/2021
 14/04/2021
 Yes
 No

 HRA research summary
 28/06/2023
 No
 No