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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

Registration date
30/10/2019

Overall study status
Stopped

Last Edited
26/09/2022

Condition category
Circulatory System

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] 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
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Study website
https://www.imperial.ac.uk/department-surgery-cancer/research/surgery/clinical-trials/chaps-trial/

Contact information

Type(s)
Scientific

Contact name
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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

01/05/2019

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
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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
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United Kingdom
TR1 3HD

Study participating centre
Bolton NHS Foundation Trust
The Royal Bolton Hospital
Minerva Road
Farnworth
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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
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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