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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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# Contact information

### Type(s)
Scientific

### Contact name
Miss Rebecca Lawton

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# Additional identifiers

### Clinical Trials Information System (CTIS)
Nil known

### ClinicalTrials.gov (NCT)
NCT04103112

### Protocol serial number
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

## Study type(s)
Treatment

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

### Key secondary outcome(s))
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

### 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

## Healthy volunteers allowed
No

## Age group
Adult

## Lower age limit
18 years

## Sex
All

## 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**
United Kingdom

England

Wales

**Study participating centre**
**Imperial College Healthcare NHS Trust**
St. Marys Hospital
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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
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**Study participating centre**
**University Hospitals Birmingham NHS Foundation Trust**
Trust HQ, PO Box 9551
Queen Elizabeth Medical Centre
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B15 2TH

**Study participating centre**
**Royal Free London NHS Foundation Trust**
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NW3 2QG

**Study participating centre**
**London North West University Healthcare NHS Trust**
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HA1 3UJ

**Study participating centre**
**Hampshire Hospitals NHS Foundation Trust**
Aldermaston Road
Basingstoke
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RG24 9NA

**Study participating centre**
**Basildon and Thurrock University Hospitals NHS Foundation Trust**
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SS16 5NL

**Study participating centre**
**The Newcastle Upon Tyne Hospitals NHS Foundation Trust**
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NE7 7DN

**Study participating centre**
**East Cheshire NHS Trust,**
Macclesfield District Hospital
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SK10 3BL

**Study participating centre**
**Salisbury NHS Foundation Trust**
Haematology Department
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**Study participating centre**
**Barking, Havering and Redbridge University Hospitals NHS Trust**
Queens Hospital
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**Study participating centre**
**Maidstone & Tunbridge Wells NHS Trust Hq**
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**Study participating centre**
**North Cumbria Integrated Care NHS Foundation Trust**
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**Study participating centre**
**Royal Hull Hospitals NHS Trust**
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**Study participating centre**
**Countess of Chester Hospital NHS Foundation Trust**
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**Study participating centre**
**University Hospital Southampton NHS Foundation Trust**
Cardiovascular and Thoracic Surgery
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**Study participating centre**
**Yeovil District Hospital NHS Foundation Trust**
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**Study participating centre**
**Royal Cornwall Hospitals NHS Trust**
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**Study participating centre**
**Bolton NHS Foundation Trust**
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**Study participating centre**
**Nottingham University Hospital NHS Trust**
Queens Medical Centre Campus
Haemostasis and Thrombosis department D Floor East Block
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**Study participating centre**
**Derby Teaching Hospitals NHS Foundation Trust**
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**Study participating centre**
**York Teaching Hospital NHS Foundation Trust**
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**Study participating centre**
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# Sponsor information

**Organisation**
Imperial College of Science, Technology and Medicine

**ROR**
https://ror.org/041kmwe10

# Funder(s)

**Funder type**
Government

**Funder Name**
Health Technology Assessment Programme

**Alternative Name(s)**
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

**Location**
United Kingdom

# Results and Publications

**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 |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |