CHAPS TRIAL SUMMARY

Sponsor: Imperial College London

The CHAPS study team are looking for Participating Organisations/Principal Investigators to recruit to the study. Contact Sarrah Peerbux (s.peerbux@imperial.ac.uk; Trial Manager) for more information about how you can take part.

TITLE

Compression Hosiery to Avoid Post-Thrombotic Syndrome (CHAPS)

OBJECTIVE

To measure the difference in incidence of post-thrombotic syndrome at a median of 18 months follow up after first, acute DVT between standard clinical care (anticoagulation) and the intervention arm (a graduated compression stocking and the standard clinical care (anticoagulation)).

FUNDER

National Institute for Health Research (NIHR): https://fundingawards.nihr.ac.uk/award/17/147/47

DESIGN

Multi-centre, pragmatic, blinded outcome assessment, randomised controlled trial. The trial will follow patients up for a median of 18 months (range 6 – 30 months) and will be conducted in approximately 11 secondary care Trusts in the United Kingdom.

SAMPLE SIZE

A total of 864 patients will be recruited, in 1:1 allocation between the two randomised arms.

ELIGIBILITY CRITERIA

Inclusion Criteria

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

Exclusion Criteria

- Life expectancy < 2 years
- Contraindication to wearing graduated compression stockings
- Previously intolerant of or already wearing graduated compression stockings for more than 1 month.
- Ankle brachial pressure index (ABPI) <0.8 or pedal pulses absent
- Bilateral deep vein thrombosis
- Previous chronic venous insufficiency of C5 or C6 status
- Pre-existing post thrombotic syndrome, significant leg pain (e.g. knee arthritis, spinal claudication) or oedema (e.g. lymphoedema).
- Newly diagnosed cancer, metastatic cancer, or cancer undergoing active treatment or palliation
- Contraindication to anticoagulation
- Known allergy to fabric in compression stockings

PRIMARY ENDPOINT

The primary outcome is any incidence of Post Thrombotic Syndrome (PTS) using the validated Villalta criteria (Appendix 1) over a median 18 month follow up (range 6 to 30 months). The primary outcome will be assessed on up to three occasions (6 and 12 months post randomisation, and at study end) depending on an individual participant's length of follow up (minimum 6 and maximum 30 months)

SECONDARY ENDPOINTS

- Venous ulceration incidence as measured by the validated Villalta criteria
- Employment status-(change in number of days working from baseline)
- Change in disease-specific and generic quality of life- VEINES-QoL and EuroQoL EQ5D scales from baseline over 6m, 12m and end of study visit
- Adherence to stockings and anticoagulants- patient self-report
- Cost-effectiveness of stocking prescription- Incremental cost-effectiveness ratio (ICER) from the EQ-5D questionnaire, with appropriate sensitivity analysis

Applicants

Professor Alun Davies, Imperial College London (CI)

Professor Beverley Hunt (Professor of Thrombosis and Haemostasis, King's College London)

Professor Andrew Bradbury (Sampson Gamgee Professor of Vascular Surgery, University of Birmingham)

Mr Ankur Thapar (Consultant Vascular Surgeon, Basildon and Thurrock University Hospitals)

Professor John Norrie (Director of the Edinburgh Clinical Trials Unit, University of Edinburgh)

Professor Dame Nicky Cullum (Professor of Nursing, University of Manchester)

Professor Rob Horne (Professor of Behavioural Medicine, University College London)

Dr David Epstein (Health Economist, University of Granada)

Miss Rebecca Lawton (Trial Manager, Imperial College London)

Mr Manjit Gohel (Consultant Vascular Surgeon, Cambridge University Hospitals NHS Foundation Trust)

Mr Joseph Shalhoub (Consultant Vascular Surgeon, Imperial College Healthcare NHS Trust)

Miss Annya Stephens-Boal (Executive Officer, Thrombosis UK)

Sites to date

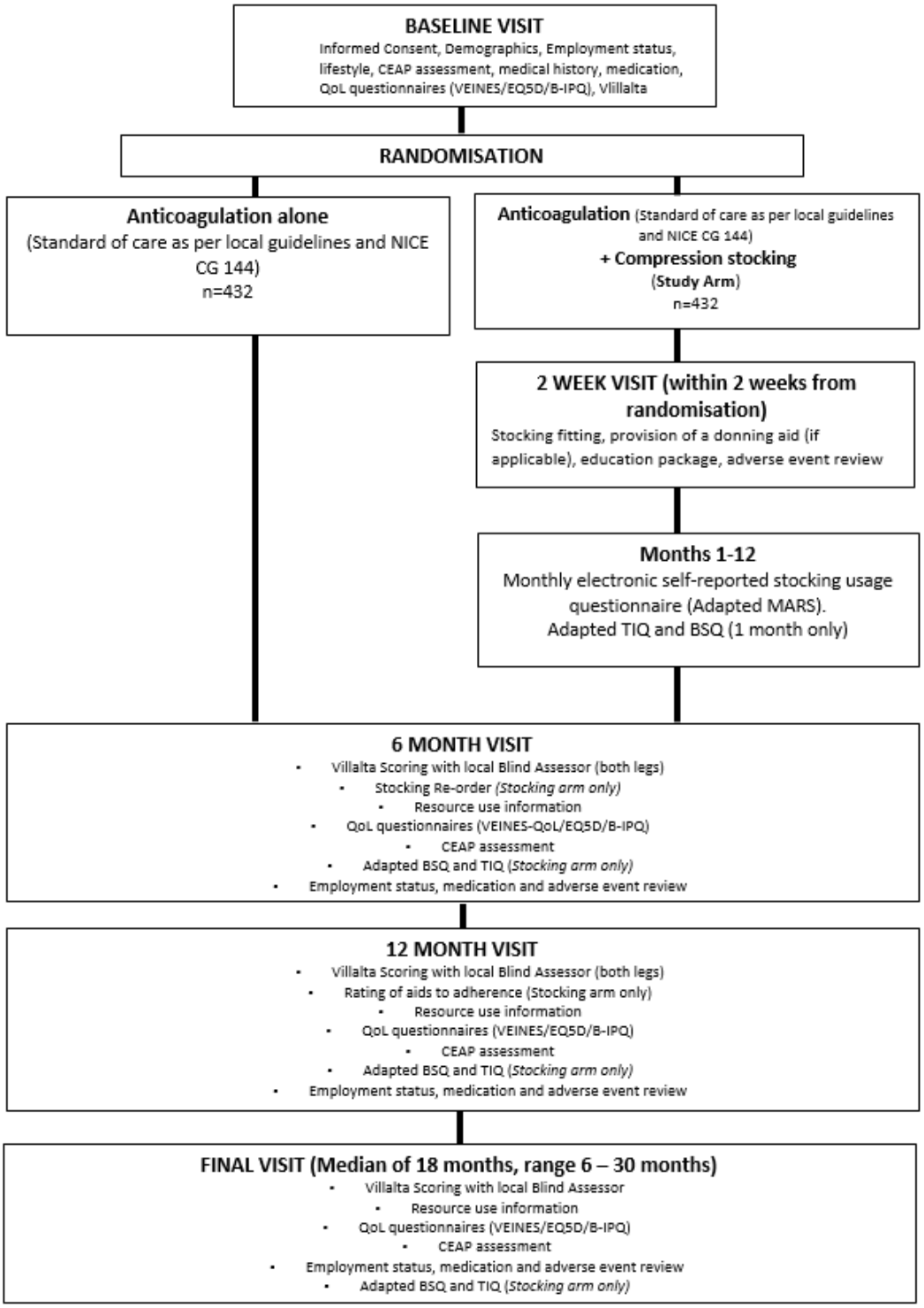
- Imperial College Healthcare NHS Trust
- Guy's and St Thomas' NHS Foundation Trust
- King's College Hospital NHS Foundation Trust
- Cambridge University Hospitals NHS Foundation Trust
- University Hospitals Birmingham NHS Foundation Trust
- Royal Free London NHS Foundation Trust
- London North West University Healthcare NHS Trust
- Hampshire Hospitals NHS Foundation Trust
- Basildon and Thurrock University Hospitals NHS Foundation Trust
- The Newcastle Upon Tyne Hospitals NHS Foundation Trust
- East Cheshire NHS Trust

Trial Steering Committee members

- Dr Peter McCallum (Chair): Senior Lecturer in Haematology, Queen Mary University of London
- Dr Susie Shapiro: Consultant Haematologist, University of Oxford
- Mr Isaac Nyamekye: Consultant Vascular Surgeon, Worcestershire Acute Hospitals NHS Trust
- Dr Stephen Gerry: Senior Medical Statistician, University of Oxford

Data monitoring committee members

- Dr Richard Bulbulia: Consultant Vascular Surgeon, Cheltenham General Hospital
- Professor Richard Haynes: Professor of Renal Medicine and Clinical Trials, University of Oxford
- Dr Natalie Staplin: Senior Statistician, University of Oxford
- Mr Keith Poskitt: Consultant General and Vascular Surgeon, Gloucestershire Hospitals NHS Foundation Trust


BASELINE VISIT
Informed Consent, Demographics, Employment status, lifestyle, CEAP assessment, medical history, medication, QoL questionnaires (VEINES/EQ5D/B-IPQ), Vlillalta
RANDOMISATION
Anticoagulation alone
(Standard of care as per local guidelines and NICE CG 144)
n=432
Anticoagulation (Standard of care as per local guidelines and NICE CG 144)
+ Compression stocking
(Study Arm)
n=432
2 WEEK VISIT (within 2 weeks from randomisation)
Stocking fitting, provision of a donning aid (if applicable), education package, adverse event review
Months 1-12
Monthly electronic self-reported stocking usage questionnaire (Adapted MARS).
Adapted TIQ and BSQ (1 month only)
6 MONTH VISIT
Villalta Scoring with local Blind Assessor (both legs)
Stocking Re-order (Stocking arm only)
Resource use information
QoL questionnaires (VEINES-QoL/EQ5D/B-IPQ)
CEAP assessment
Adapted BSQ and TIQ (Stocking arm only)
Employment status, medication and adverse event review
12 MONTH VISIT
Villalta Scoring with local Blind Assessor (both legs)
Rating of aids to adherence (Stocking arm only)
Resource use information
QoL questionnaires (VEINES/EQ5D/B-IPQ)
CEAP assessment
Adapted BSQ and TIQ (Stocking arm only)
Employment status, medication and adverse event review
FINAL VISIT (Median of 18 months, range 6 – 30 months)
Villalta Scoring with local Blind Assessor
Resource use information
QoL questionnaires (VEINES/EQ5D/B-IPQ)
CEAP assessment
Employment status, medication and adverse event review
Adapted BSQ and TIQ (Stocking arm only)