

IN THIS ISSUE:

- CHAPS re-start
- Interview with Andy Stepstone
- Study amendments

Staff updates



Thank you ♥

To all our study nurses who were re-deployed during the first wave of Covid-19, thank you for your service to the NHS. We look forward to having you back on the CHAPS trial when your site is ready to go!

CHAPS Restart!

It's been a long and strange year with Covid-19 pausing set up and recruitment across all CHAPS sites. We are slowly looking forward to sites re-opening and getting patients recruited again to this important clinical trial.

Compression Hosiery to Avoid Post thrombotic Syndrome (CHAPS) is an NIHR HTA funded trial designed to measure the difference in incidence of post-thrombotic syndrome (PTS) after first, acute DVT between standard clinical care (anticoagulation) and the intervention arm (a graduated compression stocking and the standard clinical care (anticoagulation).

Congratulations to the following sites who have all had a Site Re-activation Visit are now open to recruitment::

- **Hampshire Hospitals NHS Trust**
- **Guy's and St Thomas' NHS Foundation Trust**
- **Basildon and Thurrock University Hospitals NHS Foundation Trust**
- **Imperial College Healthcare NHS Foundation Trust**

There will be a prize for the site who randomises the first patient into the trial following the study pause.



This study/project is funded by the National Institute for Health Research (NIHR) Health Technology Assessment programme (project reference 17/147/47). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

Interview...



If you would like to get involved as a PPI rep contact: chapstrial@imperial.ac.uk

Andy Steptowe, 69, is a retired IT consultant. Twenty years ago, he was placed on anticoagulation drugs for life after a second massive deep vein thrombosis. He currently sits on the CHAPS Trial Steering Committee as a patient representative.

How did you get involved in research?

In order to better understand my condition and get support, I contacted the charity Anticoagulation UK. After receiving wonderful help, I joined the charity and they asked me to carry out small pieces of work for them from time to time. When I retired seven years ago, I was looking for voluntary work in order to still be a productive member of society and they first asked me to become a patient advisor and then an ambassador for the charity. A while ago the chance to provide support to the vascular research team at Charing Cross Hospital became available and I jumped at it. This led to the opportunity to being a PPI representative on the CHAPS trial.

Why do you think it is important for researchers to involve patients and members of the public in clinical research?

Patients and members of the public can bring practical



experience to the research, which researchers may not have. Professionals in all fields tend to assume others will understand the complicated technical language they use, so involving patients and members of the public helps with communication to people taking part in the trials.

What do you enjoy about being the PPI representative for the CHAPS trial?

It enables me to give back to

society in an area which I have some knowledge. It also allows me to keep up to speed on what is happening in the vascular arena and use this in my other charity roles.

Is there any advice you would give to people thinking of getting involved in PPI?

Even though I am an amateur working with professionals, I have always been made to feel that my opinions matter, so if you are given the chance to do this, go for it!

Amendments

The CHAPS trial has processed a number of amendments since the study pause. The amendments are summarised in the table below.

Substantial Amendment 1
Correction of typographical errors throughout the document for stockings and to correct name of BMQ questionnaire to BSQ
Addition of a letter to send to participants asking them to complete the health related QoL and a reminder letter if the participant has not responded to the first.
Clarification of adverse event reporting in the study protocol.
Substantial Amendment 2
Patient information sheet and informed consent for participants to take part in the process evaluation. Topic guide for the CHAPS process evaluation qualitative interviews.
Substantial Amendment 3
CHAPS protocol (v4.0, 25/06/2020) detailing the change in stocking pressure from UK Class II (18-24 mmHg) to EU Class II (23- 32 mmHg) and information about Medi supplying the stockings to all patients. Addition of updated NICE guideline [NG158] which replaces NICE guideline [CG144]. Addition of reference 1 to provide clarity on the definition of the exclusion criteria. Update in the protocol to say the 2 week visit can be performed over the phone or via video call if restrictions prevent the participant attending in person.
Addition of a patient leaflet- Information About Your Stockings (v1.0, 25/06/2020) to be sent at 3 months to patients in the stocking arm.
Updated Patient information Leaflet v3.0

IMPORTANT LINKS:



<https://redcap.clinicaltrials.ed.ac.uk/>



@TrialChaps

**Imperial College
London**

<https://www.imperial.ac.uk/department-surgery-cancer/research/surgery/clinical-trials/chaps-trial/>

GET IN TOUCH:

email: chapstrial@imperial.ac.uk

address: Section of Vascular Surgery
Room 14, 4th Floor East Wing, Charing Cross Hospital,
Fulham Palace Road, London, W6 8RF

tel: 0203 311 5204

A list of up to date study documents are now available for download on the Imperial College website. If you choose to download these please ensure that you add your local site headers to anything that will be given to potential participants.

<https://www.imperial.ac.uk/department-surgery-cancer/research/surgery/clinical-trials/chaps-trial/>

