Imperial College London



CHAPS TRIAL NEWSLETTER

Issue 1, June 2020

IN THIS ISSUE:

- NIHR Restart Framework
- Staff updates
- Data entry tips!

Staff updates



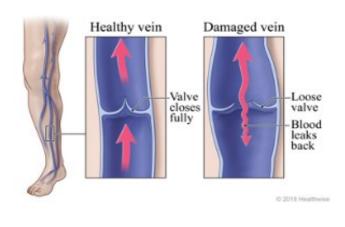
Chief Investigator of NESIC Professor
Alun Davies has been elected Fellow of
the Learned Society of Wales! The
Fellowship brings together experts
from across all academic fields to
promote research, inspire learning,
provide independent policy advice and
promote awareness of how the
sciences and the arts, humanities and
social sciences benefit society.

CHAPS

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).

What is the post thrombotic syndrome (PTS)?

Deep venous thrombosis (DVT) occurs in approximately 1-2 per 1000 adults in the UK and just under half will go on to develop lifelong disability from PTS. PTS is defined as "chronic venous symptoms or signs secondary to deep vein thrombosis" e.g. lifelong leg pain, oedema and skin changes such as itching and peeling skin. Around 5% of patients may go on to develop a venous ulcer. The pathophysiology of post-thrombotic syndrome is sustained venous hypertension from venous outflow obstruction and valvular incompetence.



NIHR Restart Framework

The NIHR Website has now been updated with a <u>statement</u> on the NIHR Framework for Restart. With this new phase of the pandemic, where the number of new cases of COVID-19 is declining and a significant portfolio of nationally prioritised urgent public health studies are actively recruiting participants, the NIHR believes the time is right to work towards of restoration of a diverse and active portfolio of research funded and/or supported by the NIHR including both non-COVID-19 research and important COVID-19 research which does not meet our urgency criteria.

CHAPS is funded by the NIHR and we hope that on-site visits can be fully restored soon. To help initiate this process, the NIHR has developed a 'Framework for restart', which is a guidance document to support local decision-making. We appreciate the pace of this restart is Trust-specific and Trust's need to ensure they have capacity and readiness for on-site visits. If on-site visits are not possible, please continue to perform follow-up visits remotely following the guidance we have previously shared.

Sites: The study will take place in 11 hospitals in the UK with Imperial College acting as the coordinating centre.

1. Imperial College Healthcare NHS Trust 2. Cambridge University Hospital NHS Foundation Trust 3. Guy's and St Thomas' NHS Foundation Trust 4. King's College Hospital NHS Foundation Trust 5. London North West University Healthcare NHS Trust 6. Basildon and Thurrock University Hospitals NHS Foundation Trust 7. Hampshire Hospitals NHS Foundation Trust 8. Newcastle upon Tyne Hospitals NHS Foundation Trust 9. University Hospitals Birmingham NHS Foundation Trust 10. Royal Free London NHS Foundation Trust 11. Cardiff and Vale University Health Board.

The Clinical trials unit is based in Edinburgh, Scotland.

We are working closely with R&D departments to get the remaining sites open to recruitment as soon as possible. Do let us know if you anticipate any delays.



IMPORTANT LINKS:



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



@TrialChaps



Imperial College London

https://www.imperial.ac.uk/departmentsurgery-cancer/research/surgery/clinicaltrials/chaps-trial/

GET IN TOUCH:

email: chapstrial@imperial.ac.uk;
r.lawton@imperial.ac.uk

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

tel: 0203 311 5204

Data entry tips!

The trial coordinating centre has produced a useful guide that addresses most of the queries you may have as you start to enter data into the REDCap database. The current guide is version 4.0, let the coordinating centre know if you need a copy.

CHAPS REDCap Guide

Setting Up a User Account

To obtain access, forecast complete the eCVF access from provided by the Trial Manager. RDCap can be accessed here: Purplemed, accessed here: Purplemed accessed here:

Queries: For the sites that are on board there may be queries that you need to action in the database. You can see if a query has been raised on a data point as a yellow speech bubble will be displayed. Click on the bubble to see what the query is and once the item is resolved it will be checked by the trial coordinating centre.

Popliteal vein



The trial coordinating centre will send you monthly listings of missing data but you can also check items of missing data at your site by generating your own reports. You can create a report from the left hand menu under 'reports'.

