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**Compression Hosiery to Avoid Post-Thrombotic Syndrome**

**(CHAPS)- Process Evaluation Sub Study**

**ISRCTN**: **73041168**

**HRA/REC Reference: 19/LO/1585**

**IRAS 263041**

**Sponsor Reference: 19CX5434**

***Acknowledgement***

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***Disclaimer***

*The views expressed in this publication are those of the author(s) and not necessarily those of the MRC, NHS, NIHR or the Department of Health.*

# PATIENT INFORMATION SHEET AND INFORMED CONSENT DOCUMENT

*You have been invited to take part in a sub study of the CHAPS clinical trial. Before you decide whether to accept, we would like to explain why this sub study is being carried out and what it will involve.*

*Please read this information carefully, and discuss it with others if you wish. Ask us if anything is unclear, or if you would like more information.*

* *Part 1 tells you the purpose of this study and what will happen to you if you take part.*
* *Part 2 gives you more detailed information about the conduct of the study.*

*Please take your time to decide whether or not you wish to take part.*

**Thank you for reading this information sheet.**

**Part 1**

**What is the purpose of the study?**

Patients with a deep vein thrombosis (DVT) may develop long-term symptoms, e.g. 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 is a smaller sub study of the main CHAPS trial that you are already taking part in. The sub study aims to look at reasons why some patients use compression stockings regularly and other patients do not. If you agree to take part in this sub study you will be interviewed once on the telephone by a qualitative researcher from University College London (UCL).

**Why have I been chosen?**

You have been invited to consider this sub study because you are a participant in the CHAPS trial and you were randomly allocated to the group of patients who wear compression stockings as well as taking a blood thinning medicine (anticoagulant).

**Do I have to take part?**

No, participation in this sub study is entirely voluntary. If you do decide to take part you will be given this information sheet to keep. You will also be asked to sign a consent form, separate to the one you have already signed for the main CHAPS trial. You are still free to withdraw at any time from either study and without giving a reason. If you decide not to take part in the sub study, you will continue to take part in the main CHAPS trial. You do not have to give a reason for not taking part and your treatment and care will not be affected in any way.

**Tell me more about the sub study**

Compression stockings have been used safely in the UK for about 50 years. They contain an elastic fibre designed to fit tightly around the legs. These specialist stockings are tighter around the ankle, with the level of compression gradually decreasing up the garment.

The pressure created by the stockings helps blood flow up the leg, allowing blood to flow freely to the heart and not pool in the leg which can result in pain and swelling.

Many studies have shown that some patients find it easy to wear stockings every day, whilst other patients may find it more difficult or might give up wearing stockings after they have been prescribed by the doctor. There may be many different reasons why some people wear them regularly and others don’t and we want to find out more information by interviewing participants who are taking part in the CHAPS trial.

**What will happen to me if I take part?**

If you choose to be involved in the sub study, you will be interviewed for about an hour on the telephone by a researcher at University College London, at a time convenient to you.

**Research interview**

If you decide to participate in the sub study, the following steps will be taken:

* Your research nurse will first ask you to sign the consent form to confirm that you would like to be included (you will be given a copy).
* Your research nurse will then pass on your name, contact details and a copy of your consent form to a researcher at University College London who will then contact you to arrange a time to conduct the telephone interview.
* The interviewer, with your permission, may audio record your conversation and will take notes of what is discussed in the interview.
* The interview will last around an hour. You will be asked questions about your views on wearing compression stockings. There are no right or wrong answers, the interviewer will want to hear your experiences both positive and negative.
* The interview will be analysed by the researcher from University College London and then written up in a medical journal

**What will be done with the information from the interview?**

The researcher will use a digital recorder to record the conversation so that it can later be analysed, they will also take some written notes. You will not be identified by name, and no identifying information will be recorded in the notes. The recordings will be transcribed (written up) and all the comments analysed together, to give a fuller picture of people’s opinions. The recordings and notes will be stored safely and treated in the strictest confidence. We may use direct quotations of what you said in the interview, but this will always be anonymous and no one will be able to tell it was you who said it.

## What are the possible benefits of taking part?

We cannot promise the study will help you but the information gained from the interview will help doctors and researchers to understand patients views on wearing stockings.

You will receive a £30 shopping voucher to thank you for participating in this interview.

## Will my taking part be kept confidential?

Yes, it will. If you decide to participate, the information collected about you will be handled strictly in accordance with the consent form that you have signed and also the 2018 Data Protection Act. Please refer to Part 2 for further details.

**This completes Part 1 of the Information Sheet. If the Information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.**

**Part 2**

**What if something goes wrong?**

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigator (Insert name and contact details). The normal National Health Service mechanisms are also available to you. If you are still not satisfied with the response, you may your local Patient Advice and Liaison Service (PALS) which offers confidential advice, support and information on health-related matters (insert contact details). You may also contactthe Imperial AHSC Joint Research Compliance Office (Room 215, Medical School Building, St. Marys Campus, Norfolk Place, London W2 1PG. Tel: 0207 594 1872).

**Will my taking part in this study be kept confidential?**

Yes, it will. All information collected about you during the course of the research will be kept strictly confidential. With your permission, your name and data from the phone interview will be kept at University College London in accordance with the 2018 Data Protection Act.

Your contact details and a copy of your consent form will be securely passed on to the researcher at University College London who will use them to contact you to arrange the interview. These details will be stored securely and separate from the research information above. The copy of your consent form will be destroyed in confidential waste after it has been checked by the researcher. The original signed consent form will be kept at your local hospital with the other information that you have provided as part of the CHAPS trial.

All the information we collect will be stored psuedonymously using a study code and will not be identifiable as belonging to you. Whilst you are taking part in the study your contact details will be made available to the researcher at UCL, so that they can contact you to arrange the interview. This information will be deleted at the end of the study. With your permission, the interview will be audio recorded so that the UCL researcher can later listen to the recording, check it and write it down (transcribe). After transcription, the audio recording will be destroyed. The transcript will be retained by UCL until the end of the study, it will then be archived for up to 10 years.

Imperial College London is the sponsor for this study based in the United Kingdom and will act as data controller for this sub-study. This means that we are responsible for looking after your information and using it properly. Imperial College London will keep your personal data for 10 years after the study has finished in relation to subject data consent forms and primary research data.

**How we will use information about you?**

We will need to use information from you for this sub-study.

This information will include your:

• Initials,

• Name

• Contact details

This will be kept at University College London and destroyed at the end of the study.

• Sex

• Ethnicity

This will be kept at University College London

Your consent form will be kept at your local NHS site.

People will use this information to do the research or to check that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead (pseudonym). We will keep all information about you safe and secure. The link link to the code number will be destroyed at the end of the study. Imperial College London will collect information about you for the CHAPS sub study via University College London who will not provide any identifying information about you to Imperial College London.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no one can work out that you took part in the study.

**LEGAL BASIS**

As a university we use personally-identifiable information to conduct research to improve health, care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research.  This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study.

Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the [UK Policy Framework for Health and Social Care Research](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/).

**INTERNATIONAL TRANSFERS**

There may be a requirement to transfer information to countries outside the European Economic Area (for example, to a research partner). Where this information contains your personal data, Imperial College London will ensure that it is transferred in accordance with data protection legislation. If the data is transferred to a country which is not subject to a European Commission (EC) adequacy decision in respect of its data protection standards, Imperial College London will enter into a data sharing agreement with the recipient organisation that incorporates EC approved standard contractual clauses that safeguard how your personal data is processed.

**SHARING YOUR INFORMATION WITH OTHERS**

For the purposes referred to in this privacy notice and relying on the bases for processing as set out above, we will share your personal data with certain third parties.

* other employees, agents, contractors and service providers College (e.g. third parties processing data on our behalf)

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

* We need to manage your records in specific ways for the research to be reliable. This means that we won’t be able to let you see or change the data we hold about you.
* If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

**WHERE CAN YOU FIND OUT MORE ABOUT HOW YOUR INFORMATION IS USED**

You can find out more about how we use your information

* at [www.hra.nhs.uk/information-about-patients/](https://www.hra.nhs.uk/information-about-patients/)
* by asking one of the research team
* by sending an email to chapstrial@imperial.ac.uk, or
* by ringing us on [**phone number**].

**COMPLAINT**

If you wish to raise a complaint on how we have handled your personal data, please contact Imperial College London’s Data Protection Officer via email at dpo@imperial.ac.uk, via telephone on 020 7594 3502 and/or via post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ.

If you are not satisfied with our response or believe we are processing your personal data in a way that is not lawful you can complain to the Information Commissioner’s Office (ICO). The ICO does recommend that you seek to resolve matters with the data controller (us) first before involving the regulator.

**What will happen to the results of the research study?**

When the sub study is complete, we plan to inform patients of the findings by letter, email, newsletter, social media or publication on the trial website. We may ask patients if there are any other methods they would prefer. The findings will be presented at conferences and published in a medical journal. No individual participants will be identified by their real names, a made up name (a pseudonym) may be used.

**Who has organised, reviewed and funded the research and who will be supervising it?**

This research has been supported by a National Institute for Health Research, Health Technology Assessment programme grant, which is funded by the National Institute for Health Research. The Sponsor of this study (Imperial College London) will pay you for your participation in the interview. Please speak to the study nurse about how to make this claim.

The research is being co-ordinated by Imperial College London, who have overall responsibility for coordination of the study. The research has been reviewed by the National Institute for Health Research, representatives from all of the participating hospitals and organisations, and an independent National Research Ethics Committee, and the Health Research Authority (HRA).

CHAPS is supported by Thrombosis UK the UK charity for patients suffering from DVT.

**Contact Details**

If you have any further questions please discuss them with your doctor. You may also find it helpful to contact the research nurse on XXXXXX.

If you would like further information about clinical research, the UK Clinical Research Collaboration (a partnership of organisations working together on clinical research in the UK) has published a booklet entitled ‘Understanding Clinical Trials’. Contact UKCRC: website: <http://www.ukcrc.org/wp-content/uploads/2014/03/iCT_leaflet.pdf>

**THANK YOU FOR READING THIS INFORMATION SHEET**

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|  |  |
| --- | --- |
| Site ID: | Initials: |
| Participant Trial ID: | Principal Investigator Name: |

**Compression Hosiery to Avoid Post-thrombotic Syndrome (CHAPS) sub study**

**IRAS 263041**

**SUB STUDY PATIENT CONSENT FORM** Please initial box

1. I confirm that I have read and understand the information sheet dated 10/08/2021 (Version 2.0) for the above sub study and have had the opportunity to ask questions which have been answered fully.
2. I understand that my participation is voluntary and that I am free to leave withdraw at any time without my medical care or legal rights being affected.
3. I understand that sections of any of my medical notes may be looked at by responsible individuals from [institution name], from NHS Trust or from regulatory authorities where it is relevant to my taking part in this research.
4. I give permission for these individuals to access my records that are relevant to this research.
5. I agree for this interview to be audio-recorded. I understand that the audio recording made of this interview will be used only for analysis and that extracts from the interview, from which I would not be personally identified, may be used in any conference presentation, report or journal article developed as a result of the research. I understand that no other use will be made of the recording without my written permission, and that no one outside the research team at University College London will be allowed access to the original recording.
6. I understand that my phone number and email address will be stored until the end of the study securely by University College London until my participation on the study ends
7. I understand that my responses will be kept strictly confidential. I understand that I will not be identified or identifiable in the report or reports that result from the research.
8. If during the study my clinical care team determine that I have lost capacity to provide informed consent, I will be withdrawn from the study and any identifiable data collected with consent would be retained and used in the study.
9. I agree to take part in this interview.

**Optional consent section (please initial the appropriate box)**

10. I give/do not give (delete as applicable) consent for information collected about me to be used to support other research in the future, including those outside of the EEA.

Give consent Do not give consent

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Full Name of Participant |  | Date |  | Signature |
|  | | | | |
| Name of Person Taking Consent |  | Date |  | Signature |

(1 copy for participant; 1 copy for the patient’s medical notes, 1 copy for the site file)