THESEUS

TREATMENT OF HIDRADENITIS SUPPURATIVA EVALUATION STUDY

PARTICIPANT INFORMATION SHEET

INVITATION

You are being invited to take part in a research study, being run by Cardiff University and the University of Nottingham. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information.

SUMMARY

As a patient with hidradenitis suppurativa (HS), you are invited to take part in this observational research study investigating a total of five treatments; medical, surgical and laser HS treatments. You and your doctor will choose which treatment you receive, dependent on what treatment is available locally and which treatment is appropriate for your care. The effect of the treatment on the severity of your HS will be recorded over the next 12 months.

The purpose of the study is to inform the design of future HS trials and to understand how HS treatments are currently used in the UK. THESEUS will see whether patients and doctors might consider joining a future HS trial and help to select the best ways of measuring response to treatment.

DO I HAVE TO TAKE PART?

Participation in the study is voluntary and you may choose not to participate, or withdraw from the study at any time, without penalty or effect on your regular medical care. If you decide to participate, you will be given this information sheet to keep, be asked to sign a consent form, and will be given a copy for your records.

WHAT WILL HAPPEN TO ME IF I TAKE PART?

After discussion with your doctor, you will be asked to choose one of up to five HS treatments: doxycycline antibiotic capsules, a combination of clindamycin and rifampicin antibiotic capsules, laser treatment, deroofing of skin tunnels (see video link describing procedure: https://www.cardiff.ac.uk/centre-for-trials-research/research/studies-and-trials/view/theseus), or regular skin surgery provided by your hospital. A comparison of the five treatments is attached to this information sheet in a Decision Grid. You may not be suitable for all five treatments and your hospital may not be able to offer all five treatments but will be able to offer at least 4 of the interventions. Your doctor will advise you on which treatments are most suitable and available to help guide your choice. If your hospital is unable to offer you your chosen intervention, it may be possible for you to attend a neighbouring hospital to receive that intervention, subject to local arrangements and your doctor will discuss this with you. There may be a delay to receive some of the interventions and, if so, you can receive another treatment first, while you are waiting.

At the beginning of the study you will be asked about your medical history and asked to complete questionnaires measuring the severity of your HS. A routine physical examination will be conducted. Depending on your choice of treatment, safety blood tests may be needed in line with standard practice. You will then be asked to make your choice of treatment. You will be asked to return to the hospital every 3 months up to 12 months to repeat these parts of the study

For the first 12 weeks after starting your chosen intervention you will have the option to indicate your pain scoring daily by mobile phone text message. We will use a mobile communications provider to send you reminder text messages every day to ask you to return your pain score for that day. The text messages you receive and respond to will be delivered by a mobile communications company called Esendex. This will mean your mobile phone number will be stored outside of Cardiff University on the servers hosted at Esendex. We have completed a thorough assessment of Esendex's data governance procedures and are satisfied your data will be treated confidentially and will not be used for any purposes other than to contact you for this study.

You can indicate on the consent form if you are in agreement with this. If at any point you no longer want to receive the daily text reminders and wish to stop providing your pain scores, you will be able to do this by texting 'STOP' on your mobile phone. There will be no cost to you to send this STOP message.

Participants who receive the deroofing or regular skin surgery options will require wound care after the procedure. Most wound care will be provided by the practice nurse at your GP surgery after one or more wound care appointments at the hospital.

You will be asked to continue with your chosen treatment option for at least the first six months of treatment if possible and, at this point, you can switch to another treatment if you wish.

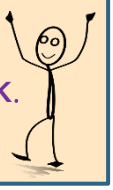
Some participants will be asked to provide feedback about the study in an interview with a member of the study team, if you agree to be contacted. Those who are invited to take part in interviews (anytime from 3 months onwards) will be provided with a separate information sheet and asked to sign a separate consent form. Following an interview you will be contacted by the study team to ensure you are ok and have no concerns about the way the interview went.

Some participants will be invited to attend an in person consensus workshop meeting to agree key design features of future RCTs of HS treatments. You are free to decline this invitation if you do not wish to take part in the workshop.

Participants who are invited to attend the consensus workshop will not be asked formally for their consent, as their attendance at the workshop will provide implied consent.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?

Deroofing and laser treatment, when offered by a recruiting centre, are not usually available for HS in the UK.



We hope that conducting this study will help to inform future treatment options for people with HS and by choosing to take part in the study, you would be helping with this.

WHAT ARE THE POSSIBLE DISADVANTAGES OF TAKING PART?

Participation in the study will require completion of some additional questionnaires not currently used in routine HS care that will take up additional time during your appointments. As with all standard care procedures your doctor or nurse will discuss the risks and benefits of your chosen intervention. The decision grid will also provide further information with regard to each intervention being offered.

WHAT WILL HAPPEN IF I DON'T WANT TO CARRY ON WITH THE STUDY?

You can withdraw from the study at any time, without providing a reason. If you stop the study, the information we have recorded about you whilst you were on the study may still be used, however, we will not collect further data about you for research purposes. You will be informed, either in writing or verbally by the research team, in a timely manner if information becomes available that may be relevant to your willingness to continue participation in the study. As an example, a new study may be published that highlights a risk (or a benefit) that was not previously known and based on this information you may decide to either stop participating in the study or to carry on.

WHAT IF SOMETHING GOES WRONG?

If you have a concern about any aspect of this study, you can speak with your doctor, GP or nurse. You can also speak to the researchers at Cardiff University who will do their best to answer your questions [see contact details below]. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure, details of which can be obtained from the hospital. In the event that something does go wrong, you are harmed during the research, and this is due to someone's negligence then you may have grounds for a legal action for compensation but you may have to pay your legal costs.

WILL MY TAKING PART IN THIS STUDY BE KEPT CONFIDENTIAL?

- Yes, we will follow ethical and legal practice and all information that is collected about you during the course of the research will be kept strictly confidential. Study data will be kept separate from personal information (names and addresses) and stored securely by Cardiff University and University of Nottingham. Only authorised persons on the research team will have access to view identifiable data. However, in some instances, authorised persons at Cardiff University (the sponsor of the study) may need to access data for monitoring of the quality of the research. All members of the research team and sponsor are trained in data protection issues and bound by the terms of the General Data Protection Regulation (GDPR) (EU 2016/679).

- Once the study is complete and it is no longer necessary to keep identifiable information or contact details, we will destroy our records of this personal information. Fully anonymised data records will be kept securely for 15 years in line with Cardiff University policies.
- If you take part in an informal interview, written transcripts of what you say will be anonymised so that it is not possible to identify who and where the data is from. Audio-recordings of the interviews will be stored in a locked cupboard within University of Nottingham and transferred onto a secure server on the Cardiff University network.
- Cardiff University, based in the UK is the Sponsor for this study.. We will be using information from you and your medical records in order to undertake this study and we will act as the Data Controller for this study. This means that we are responsible for looking after your information and using it properly.
- Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally identifiable information possible.
- NHS staff from XXX Health Boards/Trusts (depending on where you live) may use your name, NHS number and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from Cardiff University and regulatory organisations may look at your medical and research records to check the accuracy of the research study. NHS staff from XXX Health Boards/Trusts will pass these details to Cardiff University along with the information collected from you and your medical records. The only people in Cardiff University who will have access to information that identifies you will be people who need to contact you to invite you to take part in an informal interview. The

people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number, or contact details.

- You can find out more about how we use your information by visiting: https://www.cardiff.ac.uk/public-information/policies-and-procedures/data-protection or by contacting the THESEUS trial manager at THESEUS@cardiff.ac.uk or 02920 687616.

WILL MY GP BE INFORMED?

Yes. If you decide to take part in the study, we will notify your GP.

WHO IS ORGANISING AND FUNDING THE RESEARCH?

Cardiff University, based in the United Kingdom, is the sponsor for this study. The research is being funded by the UK Government, through the National Institute of Health Research Health Technology Assessment (NIHR HTA) programme.

WHAT WILL HAPPEN TO THE RESULTS OF THE RESEARCH STUDY?

A report of the research results will be completed and submitted to the funder (NIHR HTA). Results will also be published in scientific journals and presented at scientific conferences. A summary of the results will be provided on relevant websites. All results will be anonymous and you will not be identified in any report, publication or presentation.

WHO HAS REVIEWED THE STUDY?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and approved by the Research Ethics Committee (REC 4) for Wales.

You will receive a £20 voucher at the end of the 12-month follow-up period to thank you for giving your time to complete the study questionnaires.

CONTACT FOR FURTHER INFORMATION:

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THANK YOU FOR CONSIDERING TAKING PART IN THIS STUDY.

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