HidraWear AX HS Study Patient Information Leaflet and Informed Consent Form

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Study Title: HidraWear AX HS Clinical Study

NCT:04449354

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A study to assess HidraWear AX for home use in patients with Hidradenitis Suppurativa.

We would like to invite you take part in our research study.
Before you decide, we would like you to understand why the research is being done and what it will involve for you. Please read through this leaflet carefully and discuss with others if you wish.
If anything is unclear to you or you or you would like more information, please ask the researcher.
Take the time to decide whether or not you wish to take part.

What is the purpose of the study?

This study is to look at the different methods of wound care used by patients to manage their HS and to assess the performance of a new HS specific wound care product – "HidraWear AX" in terms of comfort, ease of use and impact on quality of life.

Why have I been invited?

Current research into HS wound care is mainly focused on surgical wounds and not on the everyday care for HS wounds. There are no HS specific wound care products available and patients are using standard dressings for managing a long term condition.
The researcher is interested in understanding your current method of managing your HS wounds and your wound care options / routine for HS. You have unique and valuable insights that will be very helpful to the study.

Is the study confidential?

All our research records are stored securely in locked cabinets and password protected computers. Only a few people who are closely concerned with the research will be able to view information from participants.
You will be allocated a unique identifier number which will only be known by the research nurse and you. Documents will only contain the unique identification number, so you will be not be identified by anyone conducting the study or analysing the study results.

The information that you provide in the study will be kept confidential- locked in a filing cabinet in The Hermitage Clinic. Any typed/handwritten information will be transcribed digitally saved to a password protected and secure server. This information will be safely stored for seven years after the study, and then will be destroyed

Nothing you say will be directly linked to you and no identifying information will be published.

What will happen if I agree to take part?

If you decide to take part, you will be given this leaflet and asked to sign a consent form. A copy of these will be given to you and a copy will be kept by the research team.
You will be recruited into the study. A specialist research nurse will be present and will enrol you into the study. You will see a consultant dermatologist who will assess your HS and confirm you are eligible to take part in the study.
You will then be asked some questions and to demonstrate your current HS wound care routine.
The nurse will then demonstrate the new product – HidraWear AX to you and ask you to dress your wound using the product.
You will then be given a supply of product to use at home for 3 weeks.
During the 3 weeks, you will be asked to check in daily. This will be a very quick online check in, letting us know you are doing well and how many dressings you have used. It will take less than 2 minutes each day.
You will be sent a check in reminder at 1 o'clock in the afternoon everyday that should be completed by 4 o'clock at the latest. This makes sure that we can collect the same information from each participant every day.
There will be a weekly check in also, in which you will be asked to fill in a short questionnaire.
After the three weeks, you are invited back to see the specialist research nurse.
The nurse will ask you some questions and to demonstrate your use of the new product.
You will be discharged from the study with thanks.

What will I be asked?

- You will be asked to share your experiences of HS wound care
- You will be asked to demonstrate your current method of dressing your wounds
- You will be asked to demonstrate how you use the new product-HidraWear AX
- You will be asked to complete a Dermatology Quality of Life questionnaire on the first day, the 7th day, 14th day and final day

- You will be asked to check in daily by filling out a very quick form online This will take less than 2 minutes.

Do I have to take part?

Any participation in research is voluntary.
You are free to decide whether or not to take part.
If you do decide to take part, you are free to withdraw at any time.

How long will the day 1 and day 21 visit last?

We expect the first visit to last 1 and a half hours and the second visit to last for 1 hour
The daily check in should take less than 2 minutes and the weekly Dermatology Quality of Life Surveys should take less than 10 minutes.

What are the benefits/risks of taking part?

You will have the opportunity to talk about your experiences and
You will be using a product that has been designed and developed specifically for HS
You will be contributing valuable feedback to the designers of the product

The risks involved are minimal. We have carried out a risk assessment which can be provide to you on request.
You will be asked to measure your temperature daily for the duration of the study. This is to control the very unlikely risk of skin infection occurring.

What happens if I get a high temperature during the study?

A high temperature is called pyrexia.
Pyrexia is an exclusion criteria for the study. If you have a raised temperature (over 38 degrees) you will not be enroled into the study.
If you experience pyrexia during the study, you must contact the research nurse.
The nurse will ask you to recheck your temperature again in one hours time, without the use of paracetamol or ibuprofen or any medication that will reduce a temperature.
If the temperature persists, you will be advised to attend your own GP for assessment and unfortunately, as Pyrexia is an exclusion criteria, you will no longer be able to participate in the study.

If I have more questions, who can I ask?

Please feel free to ask the researcher or research assistant any questions about the study. Contact details can be found on the last page of this leaflet.
All research is looked at by an independent committee of people called a Research Ethics Committee, to protect your interests. This study has been reviewed and approved by The Hermitage Research Ethics Committee. If you are unhappy about anything to do with the research and wish to complain formally, you can do this at:

Informed Consent

HidraWear AX Pilot Study

I _____ have read the information leaflet provided to me and understood everything in it.

I understand that I am being asked to give my time to take part in a study that involves observation, surveys, daily check in and testing a new product.
I agree to carry out the study as directed. However, I understand that I can choose not to take part at any stage and this will in no way effect my future relationships with the researcher or The Hermitage Clinic.
I give my permission to be observed as required.
I give my permission for my anonymised study information to be published in the report.
I give my permission to be contacted by email and phone by the research team.

I understand that:

1) The information will be used only for research
2) My confidentiality will be maintained at all times and no identifying information will be published
3) If the related report is published on an open access basis, it may be freely accessed throughout the world.

Signed:_____ _____

Participant Date

I confirm I have explained the nature of the study to the person above who has signed this consent form.

_____ _____

Researcher / Nurse Date