Core Outcomes for ReseArch in Lichen Sclerosus

Participant Information Sheet

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What is this project about and why is it important?

Clinical trials involve research that is intended to add to medical knowledge and improve the way we treat patients. The results of a clinical trial are reported in terms of 'outcomes'. For genital lichen sclerosus (LS), outcomes that we might look at are how much itching, pain or discomfort passing urine the patient experienced in the affected area before and after treatment.

Where there are lots of trials testing the same treatment, researchers can combine the results from all the different studies in order to be more confident about the results. Unfortunately, this is only possible where researchers have measured the same outcomes in a similar way. This isn't always the case.

If all trials which examine LS reported a particular set of outcomes, it would be much easier to combine results and determine which treatments are best. When there is an agreed minimum set of outcomes to measure in clinical trials, this is called a 'Core Outcome Set'.

Why have I been invited to take part?

We are inviting people who have genital LS, the people who care for them and the health professionals who treat them, to take part in this project. It is really important that we involve patients and their relatives when we develop Core Outcome Sets because we need to know which outcomes are most important to them.

It is up to you to decide if you want to take part in this research.

What will happen if you agree to take part?

1) We will ask you to confirm your contact details and provide an email address. These details will be stored securely.

2) You will then be invited to take part in an online survey to help us decide on the most important aspects of disease 'domains' that should be included in the final core outcome set.

a) You will be shown a 'long list' of domains and the survey will ask you to rate the importance of each domain. The survey will have up to three rounds which will be sent out over a 3-month period. It is really important that all of the rounds are completed, so that we can reliably use the data. Each round will last less than 10 minutes.

b) Prior to the survey, we will send you the long list of domains and a brief explanation of medical terms. Some questions may be of a sensitive nature. If you have any issues with any questions, we can provide support.

c) To ensure your privacy these details will be stored separately on a password protected database sitting on a restricted access computer system and would only be accessed by the research team. Data

will be used for research purposes only and stored on a secure dedicated web server. Access will be restricted to the research team. Designated individuals of the University of Nottingham may be given access to data for monitoring and/or audit of the study to ensure we are complying with guidelines. This data will be retained for at least 7 years or for longer if required. You can find out more about how we use your information and to read our privacy notice at: https://www.nottingham.ac.uk/utilities/privacy.aspx/

Participants will not receive an inconvenience allowance to participate in the study.

What will happen if I don't want to complete the survey?

Your participation in this study is entirely voluntary. You can withdraw at any point during the survey for any reason, before submitting your answers by clicking the Exit button/closing the browser. The data will only be uploaded on completion of the survey by clicking the SUBMIT button. Even after you have ticked the consent box, you are free to withdraw from the study at any time without giving a reason and without your legal rights being affected. We will no longer collect any information about you or from you. However, we will keep the anonymous research data that has already been collected and stored because it becomes difficult to extract and we are not allowed to tamper with it. This is to ensure the research data is reliable and accurate. It may have already been used in some analyses and may still be used in the final study analyses.

What will happen after the survey?

The survey will yield a 'short list' of outcome domains for genital LS clinical trials. From this short list, there needs to be final agreement of the key 'core' domains. This will take place during a follow up consensus meeting. You will be informed about the details of this meeting and invited to participate. However, it is not mandatory to participate in the meeting. By being involved in the survey you are not committing to being involved in future stages of the project. However, you will be asked if you wish to continue to receive information about this project or related projects.

We would like your permission to use anonymised data in future studies, and to share our research data (e.g. in online databases) with other researchers in other Universities and organisations both inside and outside the European Union. This would be used for research in health and social care. Sharing research data is important to allow peer scrutiny, re-use (and therefore avoiding duplication of research) and to understand the bigger picture in particular areas of research. Data sharing in this way is usually anonymised (so that you could not be identified).

Contact us:

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How is this project funded?

This study is funded by a pump-priming award from the UK Dermatology Clinical Trials Network (UK DCTN, http://www.ukdctn.org).

Useful Information

Details about the Core Outcome Set for genital LS will be available on specialist websites run by the COMET (Core Outcome Sets for Effectiveness Trials), CROWN (CoRe Outcomes in WomeN's health) and CS-COUISIN (Cochrane Skin Core Outcome Set Initiative) initiatives.

CROWN initiative. www.crown-initiative.org ; COMET www.comet-initiative.org; CS-COUSIN http://cs-cousin.org.