**PEARLS Study**

**IRAS ID: 1008267**

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**Information Sheet for Young Persons Aged 12 years and over**

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| We are researchers at the University of Nottingham, and we would like to invite you to take part in one of our clinical studies called PEARLS. Please read this information carefully and discuss it with a parent, or guardian, to decide whether you would like to take part. If there is anything that is not clear, or you would like more information, please ask your doctor or nurse.  The PEARLS study involves children and adults with lichen sclerosus. We are inviting you to this research because you have been diagnosed with this condition. This information sheet is to help you understand why we do this research and what it will involve if you decide to take part. |
| **A summary of the study** |
| **What is the study about?**  Lichen sclerosus (LS) is an itchy and distressing skin condition affecting the vulva (external female genital area). If not treated it can lead to people developing further problems in the future.  Currently we do not know the best way to manage symptoms of this condition. We are looking to see if using a medicated cream twice a week, even when the itch/symptoms have gone, may help better than if using it only when it’s itchy/symptomatic.  We plan to enrol 400 women into this study and some of them will be children, or young people, like you. We will divide all participants into two groups. One group of participants will be asked to use the treatment regularly, twice a week for 12 months. This is called **“proactive”** treatment group. The other group of patients use the treatment only when they have symptoms (e.g. itching, pain or discomfort). This is called the **“reactive”** treatment group.  We will then compare effects of the treatment in each group. We will keep in touch with you for the next two years to collect more information relating to your condition. |
| **What is the purpose of the study?** |
| We are trying to find out whether it is better to treat this condition proactively (regularly, twice a week) or reactively (only in response to symptoms) to reduce flares. By knowing this, future patients can be offered the most effective treatments to help recover sooner and reduce the chance of further problems occurring. |
| **Do I have to take part?** |
| It is up to you whether you take part in the study. We will talk to you and to your parent, or guardian, about the study and answer your questions. You and your parent/guardian both will be asked to sign a form agreeing to you taking part in the study.  If you turn 16, whilst participating in the study, we will ask you to re-consent, by signing another consent form after your 16th birthday. |
| **What will happen to me if I take part?** |
| **The First Hospital Visit**  You and your parent/guardian, will be asked to sign an assent and consent forms respectively. We will also gather basic information about you, your medical history and the medication you are currently taking. We will also ask you to complete some questionnaires about yourself and your condition. If your clinician has not recently completed a clinical examination of your condition, one will be completed at this visit to confirm your eligibility for the study. If it is possible that you could become pregnant, the research doctor will talk to you about this during the visit. Anyone who is pregnant or plans on being pregnant will not be able to take part with the study. However, if you become pregnant during your participation to the study, it is important that the study team are made aware of this. If you are deemed to be ineligible, you may be referred back to your GP for further support. With your consent, a clinician will take photographs of your affected area so that they can compare at your future appointments to see if your disease has progressed. Although taking photographs is important for the study analysis, you can choose not to have these taken, but still be a part of the study. If you don’t agree with photographs being taken, the clinician will examine you and document the details of the affected area for comparison.  We will then place you in one of the two groups, known as ‘treatment groups’. The treatment schedule you will receive is allocated using a process called randomisation, which ensures that the comparison is fair and balanced. This means that neither you nor your doctor can choose which treatment is allocated to you as part of the study as this is decided randomly.  **Follow-Up Visits**  We will ask you to attend five follow up hospital visits at 3, 6, 12, 18 and 24 months after you entered the study. At these visits we will check your condition. In addition, we will ask you to complete some questionnaires at home. If you are not sure how to complete the questionnaires, you can bring them at your research appointment where you will be able to ask questions during your visit.  **Following Your Progress**  Whilst you are in this study, we will ask you or your parent/guardian about flares you may have experienced since starting the study.  **Automated texts or, mobile app notifications, as well as automated emails will be sent to you or your parent/guardian every two weeks for the next 12 months** If we do not receive answers, you/your parent or guardian will receive reminders via texts or mobile app as well as emails. If the answer still not received, a member of the study research team may contact you or your parent/guardian. |
| **What will happen if I don’t want to carry on with the study?** |
| If you and your parent/guardian, decide in the future that you do not want to take part in the study anymore, just tell your parents, doctors, or nurses. Your doctor will continue your standard treatment as usual. You are free to leave the study at any time, without giving any reason. |
| **What are the possible benefits?** |
| We do not know which type of treatment is better and that is what you will help us to find out. This study may not directly help you, but the information we collect may help other people in the future. |
| **What are the possible disadvantages and risks?** |
| Taking part in the study may not directly help you, but the information we collect from this study may help us to treat people and understand more about the condition in the future.  The type of cream you will be using in this study is normally prescribed by your doctor, but the frequency of using it may be different. Common reactions with these types of creams are stinging and irritation of the area where applied. Other side effects, which are less common, can be read in the leaflet which came with the pack of your cream. You will not have any other side-effects because of your participation in this study. |
| **How will information about me be used?** |
| Picture of research We will need to use information about you. This will include your and your parent/guardian’s initials, name, contact details, address, your date of birth, ethnicity and your NHS number, which will identify you. We will use this to contact you and your parent/guardian when needed. This will be necessary to make sure 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. All information about you will be kept safe and secure.  Once the study has finished, we will publish the results in scientific medical journals and present them at conferences. Reports will be written in a way so that no-one can work out that you took part in this study.  We will ask you to give us permission to keep your information for up to 15 years but this will be optional and you will be able to opt out. This information may include your name, initials and other details as described above. We would use this information to allow the Nottingham Clinical Trials Unit to collect further information and see if your treatment had long-term effects. |
| **Who is conducting the research?** |
| The study is done by researchers that are experts in skin conditions. They are based at the Nottingham Clinical Trials Unit which is part of the University of Nottingham.  In the event that something does go wrong, and you are harmed during the study, there are no special compensation arrangements. If you are harmed 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. The normal NHS complaints mechanism will still be available to you. |
| [**Did anyone else check the study is OK to do?**](http://hra-decisiontools.org.uk/consent/content-sheet-support.html#ten) |
| The study has been reviewed by the Sponsor, University of Nottingham, and by the Research Ethics Committee. They make sure that everything we do is suitable for children and adults. The University of Nottingham also arranges insurance for this study. |
| **What happens at the end of the study?** |
| When the study ends, your treatment will continue as normal. At the end of the study, we may send you a newsletter with a summary of the study findings, unless you ask us not to. |
| **How can I find out about this study?** |
| Your parents or guardians who care for you have more detailed information and can answer your questions. Or you can ask us on <insert local team contact> |