**PEARLS Study**

**Proactive against reactive therapy for the prevention of lichen sclerosus exacerbation and progression of disease – a pragmatic, parallel group randomised controlled trial with embedded economic evaluation and process evaluation**

**IRAS: 1008267, version number 2.0, date 05-Feb-2024**

**Participant Information Sheet for Adults**

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| 1. **You are invited to take part in our research study**
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| * The PEARLS study is looking at whether using a steroid treatment regularly to prevent flares, is better than using the treatment only when you have a flare, in patients with lichen sclerosus (LS).
* This information sheet is to help you understand why the research is being carried out and what it will involve for you if you decide to take part.
* Please take time to read this information and ask us if there is anything that is not clear to you, or if you would like more information.
* It is your decision whether to take part in this study. If you agree to take part, and you are eligible for the study, but you later change your mind, this is fine. You are free to withdraw at any time without giving a reason. If you choose not to take part in the study at all, your care will continue in the normal way.
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| 1. **A summary of the study**
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| What is the study about?Lichen Sclerosus (LS) is an itchy and distressing condition mainly affecting vulval skin (the skin around the outside of the vagina). LS can affect children and adults of any age and can affect anyone, but it is more common in women who have gone through the menopause and children before puberty. LS affects around 1 million women in the UK. It can lead to scarring if it is not treated. Scarring can cause the labia minora (inner lips) to fuse together or the entrance to the vagina to narrow. This may cause pain and discomfort and may impact patients’ everyday lives.What are we trying to find out?We do not know the best way to manage future flares of LS. Some people think that using steroid cream or ointment regularly to prevent flares may reduce symptoms overall. We want to see if using a steroid treatment regularly (e.g. twice a week, even when symptoms are controlled), is better than using it only during a flare.The study will enrol 400 female participants and randomly allocate half to use their steroid cream twice a week (**“proactive”** treatment group), and half to only use it if they experience flare/symptoms (**“reactive”** treatment group). We will then compare treatment effects in each group.  |
| 1. **What is the purpose of the study?**
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| It is important to understand the best way to treat LS to reduce the long-term impact of the condition. 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. If one treatment is found to be better than the other, patients in the future can be advised how best to manage their condition. Avoiding flares of LS and reducing scarring will improve the quality of life of patients. It will also reduce the need for additional treatments and support. |
| 1. **Why have I been invited to take part?**
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| You have been invited to take part in this study because you have been diagnosed with LS.  |
| 1. **Do I have to take part?**
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| It is up to you whether you take part in the study. We will talk to you about the study and answer any questions you may have. If you agree to take part, we will ask you to sign a consent form.  |
| 1. **What would taking part involve?**
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| At the beginning of the study a member of the research team will approach you and provide information about the study. If you agree to take part, you will be asked to sign an Informed Consent Form. With your permission, we will inform your GP or other healthcare provider about your participation in this study. This trial is only open to those who are neither pregnant nor planning to get pregnant, so if you are of child-bearing potential you should use adequate contraception. Acceptable contraceptive methods include: established use of oral, injected or implanted hormonal methods; placement of an intrauterine device (IUD) or intrauterine system (IUS); condom or occlusive cap (diaphragm or cervical/vault caps) with spermicide; true abstinence (when this is in line with the preferred and usual lifestyle of the participant); or vasectomised partner. Please notify the study research team if you become pregnant during your participation to the study.Your participation in the study will last for 24 months. You will have to attend 6 research appointments so that we can assess your condition. We will also be looking at your medical notes to check for any other problems that might be associated with the treatment. The study team will try and arrange these visits to coincide to your routine clinic appointments, but this may not always be possible. Each visit will take approximately an hour. We will reimburse the travel expenses, on presentation of receipt, if you have to attend a research visit in addition to your routine clinical appointment. We will also gift you a £5 high-street voucher for the inconvenience after each visit.First visitAt your first visit (i.e. research appointment), prior to your allocation to one of the treatment groups, you will be asked to sign a consent form, then we will gather some information about you which is relevant for the study. We will ask you to complete some questionnaires about your condition and how it affects your everyday life. The study clinician may have to examine you at this visit to confirm your eligibility for the study. If you are found to be unsuitable for the study, you may be referred back to your GP for further support. If you are suitable to enter the study, with your consent, a clinician will take photographs of the affected area so that they can compare at future appointments to see how your disease has progressed. Although taking photographs is important for the study analysis, it is not mandatory. If you don’t agree with photographs being taken, the clinician will examine you and document the details of the affected area using a diagram for comparison at your 12 and 24 months’ visits.You will then be placed in one of two treatment groups. In one treatment group, participants will be asked to use their steroid cream or ointment twice a week, for 24 months (**“proactive”** treatment group). In the other treatment group, participants will be asked to use their steroid cream/ointment only when they experience symptoms (**“reactive”** treatment group). The treatment group you are placed in will be chosen by a computer programme. This process is called randomisation. Visits 2, 3, 4, 5, and 6There will be five further follow up face-to face visits. These will be at 3, 6, 12, 18 and 24 months from your first visit. These follow up visits will involve completing study related questionnaires and a clinical examination. Additionally, at the 12- and 24-months’ visits after your first appointment, the study clinician will examine you and make detailed notes of the affected area for comparison, as described above, in the section *First Visit*. **Following your progress**Whilst you are participating in the study, we will contact you via text messages, in addition to emails, to ask you about your symptoms. You can tell us about your symptoms by choosing to reply to either text messages or app notifications. You will also be sent survey links via emails to ask about your symptoms. **These notifications will be sent every two weeks for the next 12 months.** You will be asked about flare ups since starting the study treatment. If we do not receive answers, we will send reminders by text, app notification and email. If the answer is still not received, a member of the study research team may contact you. You will also receive questionnaires to complete. These may be done online (through a link via your chosen method) or on paper via post, if you prefer. These can be completed at home. Alternatively, they can be brought to your next research appointment, where there will be an opportunity to ask questions and complete the questionnaire during your visit.**Optional qualitative sub-study**Prior to your entry to the study, you will also be asked if you are willing to be approached about being interviewed. The audio recordings of interviews will be securely transferred and transcribed in part or full by the University of Bristol employees or their authorised representatives. If you are interested to take part in these interviews, we will provide a separate Participant Information Leaflet. Your contact details, age and ethnicity will be passed to the researcher at the University of Bristol. These interviews will help us to find out about your experience of participation in the study and share thoughts how your condition is managed beyond the study. If you decide not to take part in the PEARLS study, we may ask if you are willing to be approached to take part in an interview to understand why you decided it wasn’t right for you at this time. This is optional. |
| 1. **What are the possible benefits of taking part?**
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| Taking part in the study may not directly benefit you, but the information we collect from this study may help us to treat people/understand more about the condition in the future. |
| 1. **What are the possible disadvantages and risks of taking part?**
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| The treatments that we are using are given as part of your usual care. The only difference between the study and routine care treatment is the treatment regimen. Common reactions with steroid creams and ointments are localised hypersensitivity and stinging. For less common possible side-effects, participants are encouraged to read the patient information which accompanies the treatment. No additional side effects are expected to result from participation in the study. If you experience any side effects whilst participating in the study, please ensure you inform your local study team as soon as possible.  |
| 1. **What if there is a problem?**
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| If you have concerns or questions about any aspect of this study, you should speak to the local research team, whose contact details can be found at the end of this information sheet. If any questions remain you can contact the study coordinating centre: Tel: 0115 8231609, Email: ms-PEARLS@nottingham.ac.uk. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure via <insert local NHS department, and their contact details, who deals with patients complaints, for example, local Patient Advisory and Liaison Service (PALS)>.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. |
| 1. **What will happen if I don’t want to carry on with the study?**
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| You are free to withdraw at any time, without giving any reason, and without your legal rights being affected. If you withdraw from the study the information collected will not be erased and this information may still be used in the project analysis. |
| 1. **How will information about me be used?**
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| Researchers at the Nottingham Clinical Trials Unit (part of the University of Nottingham) and the research site will need to use information from you, your medical records, or your GP for this research project. This information will include your initials, NHS number, date of birth, name, home address, ethnicity, and contact details (including phone number(s) and email(s)).  The researchers will use this information to do the research, to check your records to make sure that the research is being done properly or contact you for future research if you opt in. 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. All information about you will be kept safe and secure. Once the study has finished, some of the data will be kept so the results can be checked and you can be told what happened in the study (unless you tell us you do not want to know). Reports will be written in a way so that no-one can work out that you took part in the study. We will also ask for your consent to share your name and telephone number with Esendex, our text messaging provider and their sub-processors, if you opt to receive text message reminders whilst you are participating in the study. Once your participation has ended you will no longer be contacted but Esendex will retain the data for operational purposes for two years or until the end of the study (whichever occurs first).We will ask you to give us permission to keep your information for up to 15 years to allow the collection of further data in relation to your condition. This will also be optional and you will be able to opt out. If you do consent, the research team at Nottingham Clinical Trials Unit may use your identifiable information (name, date of birth, NHS number etc) to look at long-term effects in relation to treatment regimens. We may obtain this information from centralised NHS records, GP notes or other national healthcare databases. |
| 1. **What are your choices about how your information is used?**
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| 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. If you choose to stop taking part in the study, we would like to continue collecting information about your health from central NHS records/your hospital/your GP. If you do not want this to happen, tell us and we will stop. 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. From 7 years after the end of the study, your data collected during the study will be disposed of securely unless you consent to the collection of further data. If you give us your permission, we may keep your contact details for up to 15 years, so we can get in touch if there is any relevant future research to do with your condition and that you may be interested in taking part in.  If you do not wish for your contact details to be kept for future research, they will also be disposed of securely at the end of the study. Your anonymised data collected in this study may be used in future research. |
| 1. **Where can you find about more about how your information is used?**
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| You can find out more about how we use your information:* [www.hra.nhs.uk/information-about-patients/](http://www.hra.nhs.uk/information-about-patients/) and [www.hra.nhs.uk/patientdataandresearch](http://www.hra.nhs.uk/patientdataandresearch)
* www.nottingham.ac.uk/utilities/privacy/privacy.aspx
* [www.nctu.ac.uk/data-protection/data-protection.aspx](http://www.nctu.ac.uk/data-protection/data-protection.aspx)
* by asking one of the research team
* by emailing PEARLS@nottingham.ac.uk
* by calling the Nottingham Clinical Trials Unit on 0115 823 1609
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| 1. **Who is organising and funding this study? How has it been approved?**
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| The study is being organised by the University of Nottingham (the Sponsor) and coordinated by the Nottingham Clinical Trials Unit (NCTU). The funding for the study is provided by the National Institute for Health and Care Research (NIHR) Health Technology Assessment (HTA, Ref: NIHR135121). All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by a Research Ethics Committee (REC), South West - Central Bristol Research Ethics Committee. Patients who have previously been treated for LS have helped us plan and design this study. Patients’ representatives are also involved in the teams that oversee the running of the study. |
| 1. [**What if relevant new information becomes available?**](http://hra-decisiontools.org.uk/consent/content-sheet-support.html#ten)
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| Sometimes we get new information about your condition during the study. If this happens your research doctor will tell you about this new information and discuss whether you should continue in the study. If you decide not to carry on, your research doctor will arrange for your care to continue as normal. If you decide to continue in the study, they may ask you to sign a new Informed Consent Form. |
| **16. What happens at the end of the study?** |
| When the study ends, your treatment will continue as normal. If you were under the care of your GP prior to entering the study, you will be discharged back to their care. If you withdraw from the study, we will need to keep and use the data collected up to your withdrawal. At the end of the study the results will be published in scientific medical journals and presented at conferences. You will not be identified in any publication. We will send you a newsletter with a summary of the study findings unless you ask us not to. |
| **17. How to contact us** |
| Contact details of your local care team:<insert contact details here> |