**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**

**Parent/Guardian Information Sheet**

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| 1. **Your child is invited to take part in our research study** |
| * The PEARLS study is looking at whether using a steroid treatment regularly to prevent flares, is better than using the treatment only during 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 your child if you decide they can take part. * Please take time to read this information and ask us if there is anything that is not clear to you, or you would like more information. * We will take their opinion into account. For your child to take part in the study, both your child and you will need to agree. If you both agree that your child will take part, and they are eligible for the study, but later you or your child change the mind, this is fine. Your child is free to withdraw at any time without giving reason. If you both choose that your child will not take part, their care will continue in the normal way. |
| 1. **A summary of the study** |
| **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 steroid cream 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?** |
| It is important to understand the best way to treat LS is to reduce 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 need for additional treatments and support. |
| 1. **Why has my child been invited to take part?** |
| Your child has been invited to take part in this study because they have been diagnosed with LS. |
| 1. **Does my child have to take part?** |
| No, your child’s participation in the study is voluntary and they do not have to take part. We will talk to you both about the study and answer any questions you may have. If your child is over 12 years old, and if you both agree for the child to take part, we will ask you to sign a consent form and your child to sign the assent form. If your child is less than 12 years old, only you will be required to sign the consent form, however, your child will still be consulted. |
| 1. **What would taking part involve?** |
| At the beginning of the study a member of the research team will approach you and your child to provide information about the study. If you agree for your child to take part, you and your child will be asked to sign an Informed Consent Form and an Assent Form (where appropriate), respectively. With your permission, we will inform your child’s GP or other healthcare provider about their participation in this study. This study is only open to those who are neither pregnant nor planning to get pregnant, so if your child is of child-bearing potential they should use adequate contraception if they are sexually active. Please notify the study research team if your child becomes pregnant during their participation to the study.  Your child’s participation to the study will last for 24 months. They will have to attend 6 research appointments so that we can assess their condition. We will also be looking at your child’s 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 child’s 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 your child has to attend a research visit in addition to their routine clinical appointment.  **First Visit**  At your child’s first visit (i.e. baseline research appointment), prior to your child’s allocation to one of the treatment groups, you and your child will be asked to sign a consent form and assent form (if appropriate) respectively. Then we will gather some information about your child, which is relevant for the study. Your and/or your child will be asked to complete some questionnaires about their condition and how it affects their everyday life. The study clinician may examine your child at this visit to confirm their eligibility for the study. If they are found to be unsuitable for the study, they may be referred back to your GP for further support.  If your child is suitable to enter the study, with your consent and your child’s permission, a clinician will arrange for photographs of the affected area so that they can compare at future appointments to see if your child’s LS disease progressed. Although taking photographs is important for the study analysis, you and your child do not have to agree to this. If you or your child do not agree with photographs being taken, the clinician will examine the child and document the details of the affected area using a diagram for comparison at 12 and 24 months’ visits.  Your child 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). Which treatment group your child will be placed in will be chosen by a computer programme. This process is called randomisation.  **Visits 2, 3, 4, 5, and 6**  There will be five further follow up face-to-face visits. These will be at 3, 6, 12, 18, and 24 months from the first visit. These follow up visits will involve completing the study related questionnaires and clinical examination. Additionally, at 12- and 24-months’ visits after your child’s first appointment, the study clinician will examine your child and make detailed notes of the affected area for comparison, as described above, in the section *First Visit.*  **Following your progress**  Whilst your child is participating in the study, we will contact you or your child via automated text messages, in addition to automated emails, to ask about their symptoms. You or your child can tell us about your child’s 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 child’s symptoms.  **These notifications will be sent every two weeks for the next 12 months.** The text message will ask about flare ups since starting the study treatment. Answers can be entered on phone, app or, if preferred, on computer. If we do not receive answers, you or your child will receive reminder texts or emails. If the answer still not received, a member of the study research team may contact you/your child.  Your will also receive questionnaires to complete with your child. This may be done online (through a link via your chosen method) or on paper via post, if preferred. These can be completed at home. Alternatively, they can be brought to your child’s next research appointment, where there will be an opportunity to ask questions and complete the questionnaire during your child’s visit.  **Optional qualitative sub-study**  Prior to your child’s 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 experience of participation in the study and share thoughts how your child’s condition is managed beyond the study. If you and/or your child decide they will not take part in PEARLS, we may ask if you are willing to be approached about 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?** |
| Taking part in the study may not directly benefit your child, 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?** |
| The treatments that we are using are given as part of your child’s 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 your child experiences 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?** |
| If you have concerns or questions about any aspect of this study, you should speak to the local research team. Their contact details are at the end of this information sheet.  If any questions remain you can contact the study coordinating centre:  Tel: 0115 823 1609, Email: [ms-PEARLS@nottingham.ac.uk](mailto: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 your child is harmed during the study, there are no special compensation arrangements. If your child is 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?** |
| You are free to withdraw your child at any time, without giving any reason, and without your legal rights being affected. If your child withdraws from the study, 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?** |
| Researchers at the Nottingham Clinical Trials Unit (part of the University of Nottingham) and the research site will need to use information from your child, their medical records, or their GP for this research project. This information will include your child’s initials, date of birth, NHS number, 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 child’s records to make sure that the research is being done properly or contact for future research if you and your child opt in.  People who do not need to know who your child is will not be able to see their name or contact details, their data will have a code number instead. All information about your child 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 and your child can be told what happened in the study (unless you and your child tell us you do not want to know). Reports will be written in a way so that no-one can work out that your child took part in the study.  We will also ask for your and your child’s consent to share your and your child’s name and telephone number with Esendex, our text messaging provider and their sub-processors, if you opt to receive text message reminders whilst your child is participating in the study. Once your child’s 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 child’s information for up to 15 years to allow the collection of further data in relation to your child’s condition. This will also be optional and you and your child will be able to opt out. If you/your child do consent, the research team at Nottingham Clinical Trials Unit may use your contact details and your child’s 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?** |
| You can stop your child being part of the study at any time, without giving a reason, but we will keep information about your child that we already have. If you choose to stop your child taking part in the study, we would like to continue collecting information about their health from central NHS records/their hospital/their GP. If you do not want this to happen, tell us and we will stop. We need to manage your child’s 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 your child.  From 7 years (after the end of the study) your child’s data collected during the study will be disposed of securely unless you consent to the collection of further data. If you and your child give us your permission, we may keep your and your child’s contact details for up to 15 years. This is so we can get in touch if there is any relevant future research to do with your child’s condition and that you/your child may be interested to take part in. If you do not wish for your child’s contact details to be kept for future research, they will be disposed of securely at the end of the study. Your child’s 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?** |
| 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](mailto:ms-PEARLS@nottingham.ac.uk) * by calling the Nottingham Clinical Trial Unit on 0115 823 1609 |
| 1. **Who is organising and funding this study? How has it been approved?** |
| 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) |
| Sometimes we get new information about your child’s condition during the study. If this happens your child’s research doctor will tell you about this new information and discuss whether your child should continue in the study. If you decide your child should not carry on, their research doctor will make arrangements for their care to continue as normal. If you decide for your child to continue in the study, the research doctor may ask you to sign a new Informed Consent Form. |
| 1. **What happens at the end of the study?** |
| When the study ends, your child’s treatment will continue as normal. If your child withdraws from the study, we will need to keep and use the data collected up to their withdrawal. At the end of the study the results will be published in scientific medical journals and presented at conferences. Your child 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. |
| 1. **How to contact us** |
| Contact details of your local care team:  <insert contact details here> |