Alder Hey Children's NHS
NHS Foundation Trust

MOSAIC – Monitoring Of Salivary cortisol in Anogenital skin Inflammation treated with topical Corticosteroids

Information leaflet for parents of boys

Your son is invited to take part in a research study. Before deciding whether they wish to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information leaflet carefully. If there is anything that is not clear, or if you would like more information, please ask a member of the research team.

What is the project about?

Your doctor has given your son a steroid cream to use on their foreskin. Some of the steroid medicine in the cream may be absorbed into the body and there is a small chance that might affect your son's natural steroid levels (cortisol and cortisone). This study is looking at natural steroid levels in children using steroid creams for skin conditions affecting the genitalia (girls are also invited to join the study). The study will measure natural steroid levels in saliva.

What are cortisol and cortisone?

Cortisol and cortisone are natural steroids, known as hormones, that are made by the adrenal glands which sit just above our kidneys. Cortisol is an energy hormone. It is released into our blood as we wake up in the morning and gives us energy throughout the day. Cortisol also helps us to recover from illnesses and infections. Cortisone is a hormone that is very similar to cortisol.

Why is this project being done?

The level of natural steroids in the body may be affected when steroid creams are used on the skin, especially if the skin is naturally thin, such as the skin of the genitalia. However, doctors are not sure if putting steroid cream on the foreskin does affect natural steroid levels as nobody has looked at this. Currently the pharmacists recommend that your son is given a 'Steroid Treatment Card' just in case the cream does cause a problem. If the study finds that no-one has a problem their natural steroid levels, then we won't have to give out the cards.

What does this project involve?

If you and your son are happy to take part, we will ask you for your permission. This can be done via an electronic link to reduce the number of visits you make to the hospital.

We provide all the equipment that you need along with an instruction leaflet, we will be in touch with reminders before each study time point. Your son will be asked to collect saliva samples by chewing on a cotton wool swab for 45 seconds before they brush their teeth and before they have breakfast. We would like them to do this:

1) Each morning for 3 days before he starts using the steroid cream
2) Each morning for 3 days just after finishing the course of steroid cream
3) Each morning for 3 days a month after finishing the treatment

After your son has chewed on the cotton wool swabs, we ask you to store them in your freezer. At the end of the study you should have 9 cotton wool swabs. We ask you to bring these along the next time your son is due to see their doctor in clinic, we will be in touch to remind you a few days before. We will ask you to bring the tube of steroid cream too, so we can see how much cream you have used. Your son will not need any additional visits to the hospital and will have normal treatment as advised by their doctor. However, if the level of cortisol or cortisone in the saliva sample is very low then we will arrange for your son to see an endocrinologist (a hormone doctor). When you bring the samples back to the hospital your son will receive a £25 shopping voucher to say thank you for taking part.

What will happen to the saliva samples?

The saliva samples will be labelled with a study number and only the study team at Alder Hey will know which samples were given by your son. The samples will be sent for analysis at a specialist laboratory in Wythenshawe. If there is any saliva left over, we will store this in the laboratory at Alder Hey for use in future research in hormone levels in saliva.

Are there any risks / benefits to taking part?

We don’t think there are any risks to taking part in this study. There are no immediate benefits to your son but the information will be used to help children and young people in the future.

Do they have to take part?

No, there is no obligation to participate. If you chose not to take part it will not affect your son’s treatment in any way. If you are unsure, we can arrange for you to meet with the study team to discuss your concerns or questions. You can talk to friends and family as well.

Can I change my mind?

Yes, you can withdraw at any time without giving a reason. This will not affect your son’s treatment in any way.

How will we use information about you?

We will need to use information collected from your son’s medical records and doctors for this research project. This information will include his hospital number and date of birth. People will use this information to do the research, or to check to make sure that the research is being done properly. People who do not need to know about your son will not be able to see any identifiable details. Data will have a code number instead. We will keep all information about your son safe and secure in accordance with current guidance.

If you or your son change your mind about being in the study, we will keep any information and spit samples that we already have but will not collect any new information or samples. Once we have finished the study, we will keep some of the data so we can check the results. Non-identifiable research data will be securely stored for 10 years. Patient data will be securely stored for 5 years. The study will be reported in an anonymous fashion.

What are your choices about how your information is used?

Your son can stop being part of the study at any time, without giving a reason, but we will keep the information we have collected about your son that we already have. If you choose to stop taking part in the study, we would like to continue collecting information about your son from the hospital. If you do not want this to happen, tell us and we will stop. We need to manage your son’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 son.

Where can you find out more about how your information is used?
You can find out how your information is used at www.hra.nhs.uk/information-about-patients/, by asking one of the research team or by emailing the study chief investigator (below).

Who is doing this research?
This research is being done by a team of doctors at Alder Hey Children's Hospital.

Has the study been checked?
Yes. The project has been approved by the NHS Research Ethics Committee. The Committee is independent to the project, and they have determined that this research does not impact on your child's rights, that risks have been minimised and balanced against possible benefits, and that sufficient information has been provided to allow you to make an informed decision about participation. This research has been sponsored by Alder Hey Children's Hospital. The sponsor has overall legal responsibility for the effective set-up, running and reporting of a research study.

What if something goes wrong?
If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions (see contact details below). If you remain unhappy and wish to complain formally, you can do this by contacting the Patient Advice and Liaison Service (PALS): 0151 252 5374.

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against Alder Hey Children's Hospital but you may have to pay your legal costs.

Who do we ask about this project?
You can talk about the project with one of the project team who gave you this leaflet or you can contact the research team directly by sending an email or calling via these contact details:

Chief Investigator:
Miss Harriet Corbett TEL: 0151 282 4598 Email: harrietcorbett@nhs.net