Alder Hey Children's
NHS Foundation Trust

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

Information leaflet for girls aged 12-15

We would like you to participate in a research project. A research project is something you do when you want to answer a question.

What is this about?
This project is about the cream doctors use to treat a problem in the skin of your vulva (the area around your wee pipe). The cream has medicine in called steroid. The steroid medicine helps make your skin better.

Your body has its own natural steroids too. If you have a lot of steroid medicine, your natural steroids might not work as well, and you may feel ill.

Your doctor advises that you must have some blood tests to check your natural steroid levels whilst you use the cream. This study is looking at natural steroid levels in spit (saliva) to see if that is a better way to check than blood tests.

Why have you asked me to help?
You have been asked to help because you have been given steroid cream to put on your vulva.

What does this project involve?
If you and your parents agree to help with this project, the team ask you to collect some of your spit (saliva). You will chew on a special cotton wool roll and then you put it into the freezer. Your parents will tell you when to do the sample, you have to do it before you clean your teeth and before breakfast. We hope you can give us 9 samples. Don't worry, we don't want them all on the same day!

We will ask you to bring the samples the next time you come to see your doctor. When you bring the samples back to the hospital you will get a £25 shopping voucher to say thank you for taking part.

What will happen to my spit samples?
Your spit samples will be sent for analysis at a special laboratory. They will only be identified by a number; they will not have your name on. If there is any sample left over, we will keep it for other research studies. It will be a gift from you to us, we hope that is OK.

Are there any risks? Will I benefit if I take part?

We don't think there are any risks to taking part in this study.
There are no benefits to you though the study may help children in the future.

Do I have to take part?

No. It's completely up to you. If you are not sure you can talk to someone in the research team.

Can I change my mind?

Yes. You can change your mind at any time, it does not matter why. Just tell your parent/guardian, or the research team.

What will happen to the results of the study?

After the study, we will write a report about what we find. Let us know if you want to hear about the results.

How will we use information about you?

We use information collected from your doctor to do the project and to make sure that the research is being done properly. Your information will have a code number so people do not know your name unless they really need to. We will keep all information about you safe and secure. We will write our reports in a way that no-one can work out that you took part in the study. If you change your mind we will keep any information and spit samples that we have but will not collect any new information or samples.

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/ or by asking one of the team doing the study.

Has the project been checked?

Yes. The project has been approved by the NHS Research Ethics Committee. This committee is a group of people who are not involved in the project. They have approved this project. They also think that enough information has been given to you to allow you to choose whether to take part or not. It has also been checked by Alder Hey Children's Hospital – who are the study sponsor. They take legal responsibility for the running of this study.

What if something goes wrong?

If you are worried about anything to do with this study, you should speak to the researchers who will do their best to answer your questions (see contact details below).
If you remain unhappy and wish to make a complaint formally, you can do this by contacting the Patient Advice and Liaison Service (PALS): 0151 252 5374.

Who do I ask about this project?

You can ask the doctors that gave you this leaflet questions about the project. You can discuss the project with your parents, they have been given information too.

Chief Investigator (the person running the study):

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