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The MOSAIC study: monitoring cortisol levels in saliva of children using steroid creams on genital skin

Submission date
12/10/2023

Recruitment status
No longer recruiting

Registration date
23/10/2023

Overall study status
Ongoing

Last Edited
20/01/2026

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Steroids are important medications, but they are associated with side effects, the most serious is suppression of the adrenal glands. Adrenal suppression can be life threatening so people taking steroid medicines are given a 'Steroid Treatment Card' to help everyone know that they are at risk. Very high doses of steroid cream may cause adrenal suppression although the amount of cream that causes this problem is not well known. Recently we have been advised to give steroid treatment cards to all children given steroid cream to treat abnormal genital skin, even though the amount of cream used is quite small. This is because genital skin is thin and may absorb more steroid medicine compared to other parts of the body. There are no research studies looking at how much cream would cause a problem though blood tests in a small number of girls treated for Lichen sclerosus (who need to use more cream) do suggest a problem.

Steroid treatment cards may cause worry, some patients may not use the cream as advised because of that. This study will measure the level of children's own steroid hormones before, during and after a course of treatment with steroid cream to their genitalia. The tests will be done in a non-invasive way (no blood tests!) by measuring cortisol and cortisone in saliva. The aim is to see if the amount of cream used to treat a common problem in boys (non-retractile foreskin) and an uncommon but related condition in girls (lichen sclerosus) causes adrenal suppression. The study will recruit 50 boys and 5 girls over 1 year, if there is no sign of a problem then the study will end but if there is any suspicion of adrenal suppression then a substantive study will be designed.

Who can participate?
Any boy or girl over the age of 5 who is given steroid cream to treat a problem with their genital skin can participate in the study.

What does the study involve?
The study involves giving some spit (saliva) samples before, during and after treatment. The samples are collected early in the morning, before breakfast, on nine days in total. The samples are stored in the participants home freezer until they next come to the hospital.

What are the possible benefits and risks of participating?
There are no direct benefits from taking part but participating will help other children who need the same treatment in the future. There are no risks to taking part but it may be inconvenient to take the samples before eating or cleaning your teeth.

Where is the study run from?
Alder Hey Children's Hospital (UK)

When is the study starting and how long is it expected to run for?
September 2022 to June 2026

Who is funding the study?
Alder Hey Children's Charity (UK)

Who is the main contact?
Harriet Corbett, harriet.corbett@alderhey.nhs.uk

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Miss Harriet Corbett

ORCID ID
https://orcid.org/0000-0002-5470-1457

Contact details
Department of Surgery, Alder Hey
Liverpool
United Kingdom
L14 5AB
+44 1512824598
harriet.corbett@alderhey.nhs.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
325526

Protocol serial number
IRAS 325526

Study information

Scientific Title
Monitoring Of Salivary cortisol in Anogenital skin Inflammation treated with topical Corticosteroids

Acronym
MOSAIC

Study objectives
To determine whether potent, topical steroid creams, applied to genital skin in children, result in significant changes in early morning salivary cortisol and cortisone concentrations from baseline measurements.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 26/07/2023, Stanmore REC (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8194; stanmore.rec@hra.nhs.uk), ref: 23/PR/0764

Study design
Observational case series

Primary study design
Observational

Study type(s)
Diagnostic

Health condition(s) or problem(s) studied
Treatment of lichen sclerosus or non-retractile foreskin in children.

Interventions
Children who need to use steroid creams on genital skin will give saliva samples by chewing on a cotton wool roll and their salivary steroid levels will be measured. Girls and boys will take part but the reason for their treatment may be different.

In the study the girls will give saliva samples just before they start treatment, part way through and just after treatment to see if the saliva test is just as good as the blood tests.
Treatment takes 3 months and the study is complete once the treatment course is finished and the final set of saliva samples has been collected.

Boys, on the other hand, only need to use a small amount of steroid cream and they do not have to have routine blood tests. Boys and girls get given a ‘steroid alert card’, the card warns they might have a fall in steroid levels. In girls that can happen so the card is important but in boys the chance is very low and the card can cause a lot of worry. If the natural body steroid levels do not actually fall in boys then boys do not need to have a card. In the study boys will give saliva before their treatment, just after the treatment (after 6 weeks) and a month later, then the study is complete.

Intervention Type
Other

Primary outcome(s)
1. BOYS - change in EMSC and EMSCn from baseline to end of treatment (after 6 weeks) and one month following treatment measured by a laboratory test of salivary cortisol and cortisone
2. GIRLS - change in EMSC and EMSCn from baseline to the end of the first 4 weeks of treatment and at the end of treatment (after 3 months) measured by a laboratory test of salivary cortisol and cortisone

Key secondary outcome(s))
1. Number of patients with EMSC or EMSCn >2 standard deviations below the mean of a cohort of healthy child volunteers measured by a laboratory test of salivary cortisol and cortisone at the end of the study
2. Percentage change in EMSC/EMSCn measured by a laboratory test of salivary cortisol and cortisone at the end of the study
3. Amount of steroid used according to age and sex measured in grams of cream used from the prescribed tube at the time of returning samples
4. Acceptability of and compliance with the study protocol measured through number of samples returned and informal discussion with participants at the time of returning samples
5. Protocol completion measured by number of children completing study and number of samples actually taken compared to number expected at the end of the study
6. Adequacy of samples measured by a laboratory test of salivary cortisol and cortisone at the time of analysis
7. Number of children requiring referral to endocrinology for further evaluation measured using patient records at the end of the study

Completion date
30/06/2026

Eligibility

Key inclusion criteria
BOYS: Males 5-15 years who are treatment naïve (no steroid medication of any kind in the previous 3 months) receiving potent topical steroid for pathological or physiological phimosis.

GIRLS: Pre-pubertal females aged 5-15 years who are treatment naïve (no steroid medication of any kind in the previous 3 months) receiving very potent topical steroid for LS following diagnosis made in the paediatric gynaecology/dermatology clinics.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
5 years

Upper age limit

15 years

Sex
All

Total final enrolment
20

Key exclusion criteria
1. Patients with oral conditions which could contaminate saliva samples with blood, such as current mouth ulcers or gingivitis.
2. Patients taking additional medications which are likely to impact on cortisol levels e.g. glucocorticoids, sex steroids, thyroxine, growth hormone, insulin, metformin, opiates, loperamide and azole compounds.
3. Children with a family history of adrenal insufficiency due to an inherited condition, including congenital adrenal hyperplasia.
4. Children <5 years of age and children at high risk of choking on the cotton wool roll used to collect the saliva.
5. The treating clinician does not consider it appropriate to delay treatment whilst the family consider the study and take the pre-treatment samples.
6. Recent (within 3 weeks) ingestion of liquorice

Date of first enrolment
14/08/2023

Date of final enrolment
12/10/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Alderhey
Eaton Road
West Derby
Liverpool
England
L12 2AP

Sponsor information

Organisation

Alder Hey Children's Hospital

ROR
https://ror.org/04z61sd03

Funder(s)

Funder type
Charity

Funder Name
Alder Hey Children's Charity

Results and Publications

Individual participant data (IPD) sharing plan
The data sharing plans for this study have not yet been agreed and will be updated at a later date.

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	For boys aged 12-15 years version 1.2	24/07/2023	23/10/2023	No	Yes
Participant information sheet	For boys aged 5-11 years version 1.1	24/05/2023	23/10/2023	No	Yes
Participant information sheet	For girls aged 12-15 years version 1.2	24/07/2023	23/10/2023	No	Yes
Participant information sheet	For girls aged 5-11 years version 1.1	24/05/2023	23/10/2023	No	Yes
Participant information sheet	For parents of boys version 1.2	24/07/2023	23/10/2023	No	Yes
Participant information sheet	For parents of girls version 1.2	24/07/2023	23/10/2023	No	Yes
Protocol file	version 1.2	23/04/2023	23/10/2023	No	No