Hair cortisol level in children with and without asthma

Published: 20-02-2013 Last updated: 23-04-2024

1 To evaluate the feasibility to measure cortisol levels in hair in healthy children and children with asthma who use inhaled corticosteroids2 To evaluate differences in cortisol levels in hair in healthy children and children with asthma who use...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Adrenal gland disorders
Study type	Observational invasive

Summary

ID

NL-OMON38679

Source ToetsingOnline

Brief title Hair cortisol level in children

Condition

• Adrenal gland disorders

Synonym adrenal function, hypothalamic-pituitary-adrenal axis

Research involving Human

Sponsors and support

Primary sponsor: Medisch Centrum Leeuwarden **Source(s) of monetary or material Support:** Het wetenschapsfonds van de MCL Academie zal worden benaderd voor sponsoring

Intervention

Keyword: asthma, children, cortisol, hair

Outcome measures

Primary outcome

Cortisol levels in hair samples

Secondary outcome

Correlation between salivary cortisol levels and cortisol levels in hair samples

Association between cortisol levels (in saliva and hair) and symptomscore and

lungfunction

Study description

Background summary

Children with asthma have significant lower salivary cortisol levels than their healthy counterparts. Measurement of cortisol levels in saliva is attractive since it is non-invasive. Time of saliva collection, medication, food, stress and infection may affect cortisol levels in saliva. Recently it has been demonstrated in adults that longitudinal cortisol levels can be measured in hair. In children this has never been studied. We want to evaluate the feasibility of cortisol measurement in hair samples in children and also to determine whether cortisol levels in hair give better insight in the effect of chronic inhaled corticosteroid use on the pituitary-adrenal axis.

Study objective

1 To evaluate the feasibility to measure cortisol levels in hair in healthy children and children with asthma who use inhaled corticosteroids

2 To evaluate differences in cortisol levels in hair in healthy children and children with asthma who use inhaled corticosteroids

3 To evaluate the correlation between single measurement of salivary cortisol levels and cortisol levels in healthy children and children with asthma who use

inhaled corticosteroids

Study design

Observational

Study burden and risks

The investigator will visit the children at home to collect a hair sample and give information about the collection of a saliva . The children with asthma will also perform lungfunction. This visit will take approximately 30 minutes. The next morning the children will chew on a cotton wool swab for 1 to 2 minutes and mail this saliva sample to the hospital. There are no visits to the hospital.

We don not expect any risks for the participants

Contacts

Public Medisch Centrum Leeuwarden

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age Children (2-11 years)

Inclusion criteria

Healthy children: prepubertal (6-12 years), no use of steroids or medication with a potential effect on steroidmetabolism;Children with asthma: prepubertal (6-12 years), stable asthma (no additional use of medication in previous three months, no use of systemic steroids in previous three months, normal lungfunction (FEV1 >90% of predicted value)

Exclusion criteria

Informed consent not obtained If the child and/or parents refuses to participate or cooperate during the study

Study design

Design

Study type: Observational invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Diagnostic	

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	15-04-2013
Enrollment:	20
Туре:	Actual

Ethics review

Approved WMO

4 - Hair cortisol level in children with and without asthma 5-05-2025

Date:	20-02-2013
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO	
Date:	04-04-2013
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register CCMO ID NL43231.099.13