Salivary cortisol in children with asthma and/or rhinitis: effect of topical steroids and correlation with symptoms and lungfunction

Published: 06-09-2010
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Evaluate the effect of topical steroids on salivary cortisol levels, and assess the correlation between salivary cortisol levels, symptoms of asthma, and lungfunction in children with asthma and/or rhinitis

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

Summary

ID

NL-OMON34524

Source
ToetsingOnline

Brief title
Effect of topical steroids on salivary cortisol level in children

Condition

- Adrenal gland disorders

Synonym
adrenal function, cortisol level

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Leeuwarden

Source(s) of monetary or material Support: wetenschapsfonds Auletius Instituut (Wetenschapsfons Medisch Centrum leeuwarden) en eigen Stichting Pediatrie Leeuwarden

Intervention

Keyword: children, salivary cortisol, topical steroids

Outcome measures

Primary outcome

difference in salivary cortisol level before and during or after treatment with

topical steroids

Secondary outcome

correlation of salivary cortisol, symptoms of asthma, and lungfunction

Study description

Background summary

Collection of saliva is a well established noninvasive way to assess cortisol levels in children. We have recently demonstrated that salivary cortisol levels are significantly lower in children using inhaled and/or intranasal steroids compared to a control group. It is unknown if the reduced salivary cortisol levels are due to the chronic inflammatory disease or to the use of topical steroids.
To the best of our knowledge, salivary cortisol levels have not been determined in individual children before, during and after treatment with topical steroids. Furthermore, it is not known if there is any correlation between cortisol levels and symptoms or lungfunction.

In the present study we want to evaluate intraindividual salivary cortisol levels before, during and after treatment with topical steroids. This way we are able to determine whether topical steroids induce an additional suppression of salivary cortisol levels, and if these levels increase after discontinuation of the steroids. We also aim to study the correlation between salivary cortisol levels, symptoms of asthma, and lungfunction.

Study objective

Evaluate the effect of topical steroids on salivary cortisol levels, and assess

the correlation between salivary cortisol levels, symptoms of asthma, and lungfunction in children with asthma and/or rhinitis

Study design

All eligible children who visit our ambulatory pediatric asthma clinic in the period september 2010- september 2011, will be asked to partcipate. Standard diagnostic procedures will be performed (lungfunction and allergy test). The following data will be recorded: height, weight, body mass index, Tanner state, type of inhalation device, allergies. For newly diagnosed patients, duration of symptoms and dose of prescribed topical steroids. For patients in whom the topical steriods are discontinued, the dose of topical steroids used in the last 3 months are recorded.
In addition, the asthma symptom score will be recorded on the day the saliva is collected by using the validated asthma control test for children.

Study burden and risks

Collection of saliva by chewing on a cottonwool swab is considered childfriendly and with minimal burden. We expect no risk for the participants

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

children 6-18 years
newly referred children who are diagnosed with asthma and/or rhinitis and who are not already using topical steroids
children with stable asthma and/or rhinitis in whom topical steroids can be tapered down to zero according to international guidelines

Exclusion criteria

informed consent is not obtained
if a child is unwilling to participate during the study
a chronic medical condition other than asthma and/or rhinitis
use of oral steroids in the past 3 months
use of concurrent medication which may potentially affect steroidmetabolism

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-03-2011
Enrollment:	40

Type:	Actual

Ethics review

Approved WMO Date:	06-09-2010
Application type:	First submission
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	ID
CCMO	NL33148.099.10