Salivary cortisol response and VO2max during standardized excercise test in children with and without asthma

Published: 28-08-2014
Last updated: 21-04-2024

To determine whether the attenuated salivary cortisol response in children with asthma can be explained by the maintenance use of inhaled cortiocosteroids, the chronic inflammatory disease, or the attenuated exercise capacity.

Ethical review	Not approved
Status	Will not start
Health condition type	Adrenal gland disorders
Study type	Interventional

Summary

ID

NL-OMON41096

Source
ToetsingOnline

Brief title
Salivary cortisol response and VO2max in children with and without asthma

Condition

- Adrenal gland disorders

Synonym
adrenal response, physical condition

Research involving
Human

Sponsors and support

Primary sponsor: Martini Ziekenhuis
Source(s) of monetary or material Support: sponsoring wordt gevraagd aan het Wetenschapsfonds van het Martini Ziekenhuis

Intervention

Keyword: asthma, salivary cortisol, VO2max

Outcome measures

Primary outcome

Salivary cortisol respons and VO2max of the children with asthma compared to

the healthy children

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Secondary outcome

Correlation between salivary cortisol respons and VO2max

Study description

Background summary

It is known that children with asthma have attenuated short term and long term basal cortisol levels (Heijsman 2011, Bakkeheim, Kamps]. The clinical relevance of this finding is unclear. However, recently we demonstrated that children with asthma also have attenuated salivary cortisol repsonses during standardized exercise tests (NL 37156.000.11, Hiemstra et al, submitted). Children with asthma had a shorter time to exhaustion despite the fact that they had stable asthma and had no restrictions in physical exercise (participated in community sports and performed physicla exercise at school) The intriguing question is why children with asthma had a shorter time to exhaustion. Children with asthma have been shown to be just as physically active as their healthy counterparts.[van Gent] Is their exercise capacity really limited or is it their perception and do they stop exercise to prevent potential symptoms of asthma.
Few studies have evaluted the physcial condition of children with asthma. Children with untreated asthma appeared to have a lower exercise capacity.[Vahlkvist] On the other hand, children with stable asthma had a VO2max comparable to their healthy counterparts.[Berntsen] In another study the exercise capacity between children with asthma and healthy children was comparable provided that the daily physical activity was comparable.[Santuz] It has been reported that lower basal cortisol levels have a deleterious effect on pulmonary function.[Landstra] Hypothetically, the attenuated cortisol respons of children with asthma may affect the exercise capacity. Indeed,

Pritis et al have demonstrated that a substantial number of children with asthma have attenuated adrenal responses which improve during maintenace treatment with inhaled corticosteroids.[Priftis]
To further elucidate whether the attenuated salivary cortisol reponse is due to attenuated exercise capacity we want to compare the salivary cortisol responses of children with asthma and healthy children, and also compare the physcial condition of the children by measuring VO2max.

Study objective

To determine whether the attenuated salivary cortisol response in children with asthma can be explained by the maintenance use of inhaled cortiocosteroids, the chronic inflammatory disease, or the attenuated exercise capacity.

Study design

observational study

Intervention

exercise test
saliva will be colected before and after the 20 meter shuttle run test
VO2max will be detrmined during teh cycle test

Study burden and risks

We expect no risk for the children as only children who are used to perform physical exercise during community sports and/or physcial exercise lessons at school will be included

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Group 1: Healthy children
boys age 8-12 years
prepuberal according to Tanner stage
BMI -1.1 to 1.1 SD
No limitations to perform exercise test (participates in community sports and/or physcial exercise lessons at school);Group 2: Children with asthma
boys age 8-12 years
prepuberal according to Tanner stage
BMI -1.1 to 1.1 SD
stable asthma (no change in maintenance medication and no systemic steroids in previous 3 months)
Maintenance dose of inhaled corticosteroids < 500 microgram per day (fluticasone equivalent)
Normal pulmonary function (FEV1 > 90% of predicted value)
No limitations to perform exercise test (participates in community sports and/or physcial exercise lessons at school);Group 3: children with newly diagnosed asthma
boys age 8-12 years
prepuberal according to Tanner stage
BMI -1.1 to 1.1 SD
No use of inhaled corticosteroids and no systemic steroids in previous 6 months
Normal pulmonary function (FEV1 > 90% of predicted value)
No limitations to perform exercise test (participates in community sports and/or physcial exercise lessons at school)

Exclusion criteria

No informed consent
If exercise test are contraindicated due to physical condition or comorbidity as judged by

treating physisian
If the child does not cooperate or does not want to continue the tests
Use of medication which may potentially affect steroid metabolism

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	60
Type:	Anticipated

Ethics review

Not approved

Date:	28-08-2014
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	NL49540.000.14