Effect of standardized running test on salivary cortisol respons in prepubertal children

Published: 30-11-2010
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To evaluate if a standardized running test will elicit an increase in salivary cortisol levels in healthy prepubertal children

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

Summary

ID

NL-OMON34313

Source
ToetsingOnline

Brief title
effect of running test on salivary cortisol

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: subsidieaanvraag is ingediend bij wetenschapsfonds van het Medisch centrum Leeuwarden

Intervention

Keyword: prepubertal, running test, salivary cortisol

Outcome measures

Primary outcome

salivary cortisol response (salivary cortisol level after exercise test -

salivary cortisol level before exercise test)

Secondary outcome

not applicable

Study description

Background summary

Collection of saliva is a well established non invasive way to assess cortisol levels in children. We have recently demonstrated that children with asthma using topical steroids have a significantly lower basal salivary cortisol level (Heijsman et al, submitted). The clinical relevance of this finding is unclear. We would like to develop a noninvasive test to determine adrenal respons in children.
We have recently demonstrated that a short standardized cycling test at different intensities does not result in a measurable increase in salivary cortisol levels in prepubertal children. An explanation may be that the cycling test did not result in maximal effort. We therefore designed the present study to determine whether a standardized running test (20 meter shuttle run test) will elicit a signficant increase of salivary cortisol levels.

Study objective

To evaluate if a standardized running test will elicit an increase in salivary cortisol levels in healthy prepubertal children

Study design

Twenty healthy prepubertal children will be invited to participate. The follwing patientcharacteristics will be recorded at the beginning of the study: height, weight, body mass index and pubertal state according to Tanner criteria. All children will have a resting period of 30 minutes is to guarantee

similar baseline conditions. During this resting period instructions will be given about the running test and the collection of saliva.
The exercise test will be performed in the afternoon (between 16 and 17:00 hr). This time was chosen because there would be no interference with school attendance. Furthermore, in the afternoon the basal activity of the hypothalamic-pituitary-adrenal axis is low and therefore expected to be more sensitive to exercise induced stimulation.

After the first running test saliva samples will be analysed. If the running test elicits an increase in salivary cortisol levels the children will perform the running test again to determine the reproducibility of the salivary cortisol response.

Intervention

A running test (20 meter shuttle run test) will be performed under supervison of a physiotherapist and one of the investigators. The shuutle run test consists of running between two parallel lines set 20 meters apart. Running speed is indicated by signals emitted from a commercially avialable CD rom. Subjects start a a running speed of 8 km/h. Running speed will be increased by 0.5 km/h at one minute intervals. The children will be verbally encouraged to perform maximally.

Study burden and risks

we do not expect any risk for the children

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

prepubertal children (6-12 years)
healthy

Exclusion criteria

medication that may potentially affect cortisolmetabolism

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-12-2010
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	30-11-2010
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	NL32923.000.10