Salivary cortisol response after exercise in prepuberal children: a pilot study

Published: 01-09-2009
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In this pilot study we want to determine if a standardized cyclic ergometer test result sin a measurable and reproducible cortisol response.

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

Summary

ID

NL-OMON33480

Source
ToetsingOnline

Brief title
Salivary cortisol response after exercise

Condition

- Adrenal gland disorders

Synonym
adrenal function, cortisol response

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Leeuwarden
Source(s) of monetary or material Support: Stichting Pediatrie Leeuwarden

Intervention

Keyword: cortisol response, exercise test, prepuberal, salivary cortisol

Outcome measures

Primary outcome

Primary study parameter is the salivary cortisol response (salivary cortisol

value after the test - salivary cortisol value before the test)

Secondary outcome

not applicable

Study description

Background summary

Determination of salivary cortisol has emerged as a reliable alternative to screen for HPA axis suppression, with the advantage to be very child-friendly, cheap and easy to perform. However, assessment of basal cortisol values does not inform us about adrenal function during stress. Recent studies have demonstrated that salivary cortisol is well correlated to plasma cortisol during an ACTH test in children with adrenal insufficiency. Stress due to physical exercise results in a physiological rise of cortisol. It is not known whether a standardized cyclic ergometer test results in a measurable cortisolreponse.

Study objective

In this pilot study we want to determine if a standardized cyclic ergometer test result sin a measurable and reproducible cortisol response.

Study design

The children will perform a physical working capacity test (PWC 170) under guidance of a phyisotherapist. This is a standardized cyclic ergometer test. Children will start cycling with a resitance of 25 watt during 3 minutes. Subsequently, the resistance will be increased with 20 watt every 3 minutes until the heartrate reaches 170 beats per minute. After a minumum of 1 week the test will be repeated to determine the reproducibilaty of the test.

Intervention

submaximal standardized cyclic ergometer test

Study burden and risks

In daily life children constantly perform submaximal exercise while playing outside and while playing sports. We therefore feel that is justified tot let the children perform this submaximal cyclic ergometer test

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

prepuberal,

children who do not use any formulation containing steroids or medication known to affect steroidmetabolism.

Exclusion criteria

a physical condition or underlying disease that does not allow submaximal exercise

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):	24-11-2009
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	01-09-2009
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

Approved WMO Date:	22-02-2010
Application type:	Amendment
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	NL28491.000.09