Biological stress activity in obese children compared to normal weight controls: a pilot study.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON34281

Source
ToetsingOnline

Brief title
Stress activity in obese children.

Condition

- Other condition

Synonym
fatness, obesity

Health condition

Obesitas

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Children, Hypothalamo-pituitary-adrenal axis, Obesity, Stress

Outcome measures

Primary outcome

Area under the curve - salivary cortisol

Secondary outcome

Not applicable

Study description

Background summary

Our society has seen major structural changes in the last 20 years such as technological advancements. These changes have been affecting working patterns, social networks, and family structures. As a result of this, levels of stress have increased in society. Recently a third of children in a general population study were found to experience increased stress. Psychological stress is communicated to the body by activation of the physical stress system, with elevation of the stress hormone (cortisol) as a key mediator. Extended periods of elevated cortisol (such as in diseases like Cushing syndrome) or pharmacologic treatment with synthetic cortisol (like prednisone) lead to obesity, and its metabolic sequelae.

Recent studies provide evidence for the relationship between chronic stress and obesity in monkeys and human adults. No studies have been performed in children yet.

Study objective

The objective of this study is to analyse the association between stress and obesity in childhood. We hypothesize that obese children have higher levels of stress than normal weight controls. The key objective is to study differences in the area un der the curve of salivary cortisol in obese children as compared

to normal weight controls.

Study design

In this pilot study, 50 obese children and 50 normal weight controls in the age range 8-12 years will be enrolled after informed consent. Obesity is defined as> +2.3 BMI SDS on the curve according to the guidelines of the World Health Organization. The controls must have a BMI SDS <+1.1. Exclusion criteria are presence of a chronic disease, use of corticosteroids or beta-blockers. Data on basic characteristics and anthropometric parameters will be collected. Participants will complete questionnaires about stress perception, coping, reward sensitivity, food craving and eating behaviour. Cortisol level in a small sample of hair, cut from the back of the head (about 100 hairs) will be obtained as a marker for chronic stress. Daily stress will be measured using salivary cortisol; six salivary samples are obtained on 1 day. Salivary sampling will be performed at home after detailed instructions. The saliva samples will be sent to the laboratory by mail.

Study burden and risks

There are no risks associated with participation in this study.
This study has a low burden, only time investment. In this study only patient- and childfriendly investigations are used.

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

Obese: obesity is defined as >+2.3 BMI-SDS on the curve according to the World Health Organization guidelines.
Age 8-12 years.;Controls should have a normal weight, defined as <+1.1 BMI-SDS on the curve, and will be age- and sexmatched.

Exclusion criteria

Presence of a chronic disease
Use of cortisteroids
Use of beta-blockers

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL
Recruitment status: Recruiting

Start date (anticipated):	01-09-2011
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	20-12-2010
Application type:	First submission
Review commission:	TWOR: Toetsingscommissie Wetenschappelijk Onderzoek Rotterdam e.o. (Rotterdam)

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	NL34093.101.10