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

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Ethical review	Not approved
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON34437

Source
ToetsingOnline

Brief title
Stress activity in obese children.

Condition

- Other condition

Synonym
obesity, overweight

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

The main study parameter is the difference in stress levels in obese children

as compared to normal weight controls.

Secondary outcome

Cortisol sensitivity in obese children compared to normal weight controls.

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 children. We hypothesize that obese children have higher levels of stress than normal weight controls. The key objective is to study differences in stress levels in obese children as compared to normal weight controls. In

addition, we aim to study the association between genetic sensitivity to cortisol and obesity in childhood.

Study design

In this pilot study, 10 children with obesity and 10 normal weight controls in the age range 8-12 years will be enrolled after informed consent. 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 (± 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 instruction. The saliva samples will be sent to the hospital by mail. The very-low-dose (0.25 mg) dexamethasone suppression test will also be performed at home. Participants will take 0.25 mg dexamethasone (adjusted to bodyweight; 3.33 microgr/kg) at bedtime. The next morning post-dexamethasone cortisol is measured in saliva (7th salivary sample). The post-dexamethasone cortisol level will be used as a measure of cortisol sensitivity.

Intervention

Dexamethasone suppression test (see study design)

Study burden and risks

There are no risks associated with participation in this study. The dose of dexamethasone is so low that no side effects are expected. This study has no burden, only time investment can be called a burdening. In this study only patient- and childfriendly investigations are used.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 60
3015 GJ Rotterdam
Nederland
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 60
3015 GJ Rotterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Obesity (controlgroup: normal weight, age- and sex matched)
Age 8-12 years

Exclusion criteria

Presence of chronic disease
Use of corticosteroids
Use of beta-blockers

Study design

Design

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

Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	20
Type:	Anticipated

Ethics review

Not approved

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	NL34061.000.10