Heart rate variability in obese adolescents in relation to insulin levels during OGTT.
A pilot study

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The aim of the project is to study the relation between hyperinsulinemia and changes in autonomic tone in adolescents with obesity. We have chosen to perform a pilot study, because of lack of comparable studies in the literature.

Ethical review	Approved WMO
Status	Pending
Health condition type	Glucose metabolism disorders (incl diabetes mellitus)
Study type	Observational non invasive

Summary

ID

NL-OMON31491

Source
ToetsingOnline

Brief title
HRV in obese adolescents

Condition

- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
diabetes, Metabolic syndrome

Research involving
Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Adolescents, Heart rate variability, Insulin, Obesity

Outcome measures

Primary outcome

The main parameters in this study will be LF (ms2), HF (ms2), LF/HF ratio, TP (ms2) and SDNN (ms). These parameters give information about the state of the central nervous system. BMI (kg/m2), cortisol (nmol/l), melatonin (pgram/ml), glucose (mmol/L), insulin levels (pmol/L) and the duration of obesity (months) will be considered as possible regressors.

Secondary outcome

Not applicable

Study description

Background summary

Obesity is a fast growing major health problem throughout the Western world, in the adult as well as in the paediatric population. Since the roots of adult obesity are likely established in childhood and adolescence, this young age group deserves extra attention, in order to intervene in the process of obesity development as early as possible. In recent literature there are indications that there is an important role for the autonomic nervous system in the health problems related to obesity.

Study objective

The aim of the project is to study the relation between hyperinsulinemia and changes in autonomic tone in adolescents with obesity. We have chosen to perform a pilot study, because of lack of comparable studies in the literature.

Study design

During an OGTT (part of the routine laboratory investigation in obese adolescents), a continuous ambulatory measurement of their heart frequency will be made using the VU Ambulatory monitoring system. Cortisol and melatonin will be measured in saliva at 8 am, 4 pm and 11 pm on the day that an OGTT is performed. Use of grow curves will able us to asses the duration of obesity.

Study burden and risks

Non-invasive techniques: Ambulatory measurement of heart frequency
Cortisol and melatonin saliva test
Benefit: None
Risk: None

Contacts

Public
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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)

Inclusion criteria

Boys, Age 12-18 years, BMI>95th perc.

Exclusion criteria

Congenital or acquired heart disease, neurological disabilities, diabetes mellitus, medication that may influence the autonomic nervous system and/or insulin resistance or secretion.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2008
Enrollment:	15
Type:	Anticipated

Ethics review

Approved WMO

Date:	28-04-2008
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL20586.029.07