Evaluation of insulin resistance in obese children and adolescents referred to a paediatric obesity outpatient clinic: a follow up study.

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Primary objective: To evaluate the insulin sensitivity measured with Homeostatic Model Assessment of Insulin Resistance (HOMA-IR) in obese children and adolescents 3 years after diagnosis of insulin resistance.Secondary objectives:1. To evaluate the...

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

Summary

ID

NL-OMON39352

Source
ToetsingOnline

Brief title
CAIRO: Children and Adolescents with Insulin Resistance and Obesity

Condition

- Other condition
- Glucose metabolism disorders (incl diabetes mellitus)

Synonym
insulin resistance

Health condition

Obesitas

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis
Source(s) of monetary or material Support: geen

Intervention

Keyword: Children, Insulin Resistance, Obesity

Outcome measures

Primary outcome

Main study parameters/endpoints:

Primary endpoint is the HOMA-IR measured between 2-5 years after diagnosis of

insulin resistance.

Secondary outcome

Secondary endpoints are BMI, FPG, T2DM and quality of life between 2-5 years

after diagnosis of insulin resistance

Study description

Background summary

Overweight and obesity in children and adolescents are major health problems all over the world. One of the most important sequels of obesity is the development of type 2 diabetes mellitus (T2DM). Longitudinal studies in adults have demonstrated that insulin resistance progresses to T2DM. Particularly in children and adolescents; there is not much insight (duration, severity and contributing factors) in the actual progression of insulin resistance, which is expected to ultimately result in T2DM in most cases. Therefore further studies are needed in obese children and adolescents with insulin resistance to evaluate their status of the insulin sensitivity over the years.

Study objective

Primary objective:
To evaluate the insulin sensitivity measured with Homeostatic Model Assessment of Insulin Resistance (HOMA-IR) in obese children and adolescents 3 years after diagnosis of insulin resistance.

Secondary objectives:
1. To evaluate the following criteria in obese children and adolescents 3 years after the diagnosis of insulin resistance:
- Change in Body Mass Index (BMI)
- Change in Fasting Plasma Glucose (FPG)
- Progression to the provisional diagnosis of T2DM.
2. To evaluate quality of life in obese children and adolescents 3 years after a diagnosis of insulin resistance

Study design

This study is a cohort study in which data are gathered on the 3-year follow up of obese children and adolescents with insulin resistance.

Study burden and risks

Burden and risks as a result of this follow-up study are relatively limited because a 3-yearly follow up screening for T2DM in obese children >10 years can be considered standard care [Addendum voor kinderen bij de CBO-richtlijn *Diagnostiek en behandeling van obesitas bij volwassenen en kinderen]. After invitation for follow-up, one fasting blood-sample for each child will be collected according to the addendum.
In case the results of the screening necessitate to have further diagnostic or treatment investigations, these will be performed according to standard care (this will include an Oral Glucose Tolerance Test (OGTT)).
Besides this standard care screening, all participants are asked to fulfil 3 questionnaires about the demographic characteristics, quality of life and also dietary intake (approximately 1 hour).

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

Signed informed consent.
The need for informed consent is waived in case parents/caregivers and subjects during the visit to the outpatient clinic did not make an objection orally against the use of their clinical data. In the
latter case, routinely collected clinical and laboratory data will be used only.

Exclusion criteria

Oral objection of subject and/or parents/caregivers for use of clinical data.

Study design

Design

Study type: Observational non invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-12-2011
Enrollment:	89
Type:	Actual

Ethics review

Approved WMO Date:	21-11-2011
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	04-02-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL37741.100.11