The AIM-to-OBserve study: Adipokines and Inflammatory Markers in childhood OBesity

Published: 23-10-2009
Last updated: 10-08-2024

a) To investigate the differences in adipokines and inflammatory markers between obese and normal weight children; b) to study these differences over age, and c) to correlate adipokine/inflammatory marker profiles to clinical parameters for obesity…

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Coronary artery disorders
Study type	Observational non invasive

Summary

ID

NL-OMON33433

Source
ToetsingOnline

Brief title
AIMOB

Condition

- Coronary artery disorders
- Glucose metabolism disorders (incl diabetes mellitus)
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
adiposity, Obesity

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

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

Intervention

Keyword: Adipokines, Childhood, Inflammatory markers, Obesity

Outcome measures

Primary outcome

1) the difference in adipokine/inflammatory profiles between obese children and normal weight controls. 2) the relation between adipokine/inflammatory profiles and clinical parameters for obesity.

Secondary outcome

Not applicable

Study description

Background summary

Obesity is regarded as a state of low-grade inflammation, characterized by an increase in inflammatory makers and changing levels of adipose tissue-specific inflammatory mediators, called *adipokines*. These inflammatory changes have been associated with the development of obesity-related complications like insulin-resistance and CVD. The potential use of adipokine/inflammatory profiles as risk markers for CVD became the focus of a new Wilhelmina KinderZiekenhuis/UMC Utrecht research line.
As the first stage of this new Wilhelmina KinderZiekenhuis/UMC Utrecht research line, we would like to study differences in adipokine/inflammatory markers of obese children versus normal weight sex- and age matched controls. First, using state-of-the art MIA technology, we would like to make adipokine/inflammatory marker profiles of 70 obese* versus 70 normal weight (+ 0.5 SD-0.5 SD for age) children aged 6-16 years. Second, as differences in adipokine/inflammatory marker profiles between obese and normal weight children might vary with age, we want to study these differences over age. Finally, we would like to correlate adipokine/inflammatory marker profiles to clinical parameters for obesity (e.g. waist/hip circumference, plasma lipids).

Study objective

a) To investigate the differences in adipokines and inflammatory markers between obese and normal weight children; b) to study these differences over age, and c) to correlate adipokine/inflammatory marker profiles to clinical parameters for obesity (e.g. waist/hip circumference, plasma lipids).

Study design

Observational, case-control study

Study burden and risks

Obese children are routinely assessed for obesity-related conditions in the obesity polyclinic of the Meander hospital (Amersfoort). In case of study participation, their only burden consists of two additional 10 millilitre blood samples for study laboratory measurements, drawn during a routine venapuncture. Normal-weight sex- and age-matched controls will also be selected from the pediatric outpatient department, and only included in the study when no inflammatory condition is diagnosed, as this might interfere with the adipokine/inflammatory marker profiles. In case of study participation, the normal weight controls* burden consists of a more extensive physical examination (waist+hip circumference, bio-electrical impedance measurement, blood pressure, in addition to the routine physical examination) and two to three additional 10 millilitre blood samples for study laboratory measurements, drawn during a routine venapuncture.
Risks for the participating subjects are negligible.
Since we aim to study differences in adipokine/inflammatory marker profiles between obese and normal weight children, this study can only be performed in minors.
There is not direct benefit for participating subjects.

Contacts

Public
Universitair Medisch Centrum Utrecht

Lundlaan 6
3584EA
NL
Scientific
Universitair Medisch Centrum Utrecht

Lundlaan 6
3584EA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Patientgroup:
6-16 years of age
BMI (>30 kg/m2 projected at the age of18 years), according to international standards, see also Hirasing RA, Fredriks AM, van BS, Verloove-Vanhorick SP, Wit JM. [Increased prevalence of overweight and obesity in Dutch children, and the detection of overweight and obesity using international criteria and new reference diagrams]. Ned Tijdschr Geneeskd 2001 July 7;145(27):1303-8.;Controls:
Sex and age matched to patient group
-0.5 SD Newly referred patients to the pediatric outpatient department, by general practitioners, for the reason of:
- Suspected allergy or asthma
- Analysis of complaints of fatigue/malaise
- Prediction of final height
- Habitual constipation (i.e. constipation not explained by a disease)

Exclusion criteria

Patientgroup:
- Intoxication (smoking, i.e. sigaret use, drug-use)
- Acute illness (fever)
- Mental retardation
- Allergy with positive RAST for food/inhalation allergy and (history of) Muller class I-II reaction (i.e. severe systemic allergy/anaphylaxis)
- Asthma (based on doctors* diagnosis: history of recurrent wheezing, obstructive lung function tests with reversibility after administration of β2-sympathicomimetics, use of asthma-medication)

Controls:
- Intoxication (smoking, drug-use)
- Acute illness (fever)
- Mental retardation
Exclusion criteria for involved referrals:
- Allergy with positive RAST for food/inhalation allergy and (history of) Muller class I-II reaction (i.e. severe systemic allergy/anaphylaxis)
- Asthma (based on doctors* diagnosis: history of recurrent wheezing, obstructive lung function tests with reversibility after administration of β2-sympathicomimetics, use of asthma-medication)
- Complaints of fatigue/malaise explained by M.Pfeiffer, inflammatory or infectious illness (e.g. inflammatory bowel disease, (viral) hepatitis, rheumatologic disease)
- Assessment of height when short or tall stature (height ± 1 SD of target height (TH), so height outside TH-range) or endocrine explanation for abnormal growth pattern (e.g. growth hormone deficiency)

The exclusion-criteria are formulated on the assumption that these might influence adipokine/inflammatory profiles.

Study design

Design

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

Primary purpose: Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-01-2010
Enrollment:	140
Type:	Actual

Ethics review

Approved WMO Date:	23-10-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL28898.041.09