Genetics of childhood obesity (basic protocol for the Netherlands Epidemiology of Obesity in children study)

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Appetite and general nutritional disorders
Study type	Observational invasive

Summary

ID

NL-OMON32701

Source
ToetsingOnline

Brief title
genetics of childhood obesity

Condition

- Appetite and general nutritional disorders

Synonym
adiposity; overweight

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W,nog aan te vragen subsidies

Intervention

Keyword: children, genetics, melanocortin-4 receptor, obesity

Outcome measures

Primary outcome

frequencies of various polymorphisms and mutations in genes involved in the

regulation of motivational behaviour and satiety such as the melanocortin 4

receptor, dopamine D2 receptor, leptin, and pro-opiomelanocortin

Secondary outcome

not applicable

Study description

Background summary

The current prevalence of childhood overweight and obesity is alarmingly high. Childhood obesity is associated with considerable health risks and it resists most available treatments. There is a substantial genetic contribution to obesity. In addition, epigenetic mechanisms play a role. The known genetic risk factors for obesity explain only a limited part of the variance in body mass index (BMI). A better characterization of the genetic risk factors for childhood obesity will ultimately lead to improved treatment and prevention strategies. We propose that (epi-)genetic variation in genes involved in the regulation of addicitive behaviour and satiety plays a major role in the development of obesity. We aim to study (epi-)genetic variation in these genes using family-based association and linkage analysis in a large cohort of obese children and adolescents. In addition to the studies of common obesity, we would like to study monogenic forms of obesity. The most common monogenic form of obesity is caused by mutations in the gene encoding the melanocortin 4 receptor (MC4R). This receptor plays a central role in homeostatic aspects of energy balance. We plan to perform mutation analysis of MC4R in the cohort. Our cohort is uniquely suited to study the role of MC4R mutations in obesity.

Study objective

We propose that variation in genes involved in the regulation of motivational behaviour and satiety plays a major role in the development of obesity. We aim to identify these genes using family-based association and linkage analysis in a large cohort of obese children and adolescents.

In addition, we plan to perform mutation analysis of the gene encoding the melanocortin 4 receptor (MC4R) in our cohort with the aim to study the role of MC4R mutations in obesity.

Study design

We will establish a centre for childhood obesity at Leiden Univeristy Medical Center (LUMC). In this centre, we will collect a variety of data for diagnostic and treatment purposes. These data include anthropometric measures, oral glucose tolerance response, endocrine measures, information about dietary intake, physical activity, socio-economic status, and ethnicity. We aim to collect DNA of the patients of our centre and their parents and siblings. All patient samples will be screened for mutations in the melanocortin-4 receptor gene (MC4R). We will study the phenotypic characteristics of patients with and without MC4R mutations. If we do not find defects in MC4R in the DNA of a patient, the sample will be stored in our DNA bank for future candidate gene studies and family based association or linkage studies.

Study burden and risks

We propose to ask patients and their parents for consent to withdraw blood samples for our genetic studies. Sampling of the children and adolescents will be performed simultaneously with blood withdrawal for diagnostic purposes. Consequently, there is no extra burden for patients. Parents and siblings of the patients will undergo venipuncture once. In some cases we will collect DNA using buccal swabs or a DNA Self-Collection Kit (to collect DNA from saliva). This will be the preferred method for very young children and. In the future, this study should lead to improved treatment methods.

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

overweight or obesity; age younger than 19

Exclusion criteria

none

Study design

Design

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

Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-03-2010
Enrollment:	4000
Type:	Actual

Ethics review

Approved WMO

Date:	01-03-2010
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL31134.058.09