Prevent CardioKids

Published: 11-12-2013
Last updated: 24-04-2024

The aim of Prevent CardioKids is to evaluate to what extend disturbed vascular function markers are present in children of different weight categories and whether these are age dependent. Also differences * and relationships between * vascular...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal conditions NEC
Study type	Observational invasive

Summary

ID

NL-OMON44875

Source
ToetsingOnline

Brief title
Prevent CardioKids

Condition

- Gastrointestinal conditions NEC
- Metabolism disorders NEC
- Vascular disorders NEC

Synonym
Co-morbidities overweight/ Vasculac function markers

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: TI Food and Nutrition

Intervention

Keyword: Childhood, Comorbidity, Early diagnosis, Overweight and obesity

Outcome measures

Primary outcome

The primary endpoint is to examine the difference in micro- and macrovasculature characteristics in children with different weight classifications (lean; overweight; obese; extreme obese; morbid obese).

Secondary outcome

Secondary endpoints are differences in lipoprotein profiles, pro-inflammatory, fundus photography and OGTT profiles between different age groups, between lean and overweight/obese children and in relation with the measured micro- and macrovasculature characteristics

Study description

Background summary

Children and adolescents with overweight and obesity are predisposed to significant health problems. It is known that childhood obesity can adversely affect almost every organ system, and if left untreated, the major impact of childhood overweight is likely to be felt in the next generation of adults.

Study objective

The aim of Prevent CardioKids is to evaluate to what extend disturbed vascular function markers are present in children of different weight categories and whether these are age dependent. Also differences * and relationships between * vascular function measurements and plasma biomarkers between lean and overweight/obese children will be compared.

Study design

Longitudinal study

Study burden and risks

All exams take place during the standard care 24 hour hospitalization of the COACH program, no extra visits are required. During this hospitalization all participants receive blood sampling as standard care, for this study an extra volume of 10 mL blood will be sampled. Participants have to collect urine and faeces. Furthermore, participants will receive retinal imaging and a peripheral arterial tonometry (PAT), both non-invasive investigations. All the measurements required for this study are classified as very low risk and non-time consuming for the participants.

With little inconvenience and miminimal risks the results of this study provide information on characteristics of micro-and macrovasculature and pro-inflammatory profile in overweight and obese children of different age categories. Furthermore, comparisons can be made with children with a normal, healthy weight. This knowledge can be used to improve the health of children with overweight and obesity.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Participation in the COACH program
- Aged between 6 and 18 years (at time of inclusion)
- Overweight or obesity according to International Obesity Task Force (IOTF) criteria;For control group
- Aged between 6 and 18 years
- Normal weight according to the International Obesity Task Force (IOTF) criteria
- Undergo surgery for elective reasons

Exclusion criteria

Retardation
Inflammatory disease: auto-immune diseases, inflammatory bowel diseases, hepatitis, dermatitis, nephritis, pancreatitis, gastro-enteritis, vasculitis, salpingitis, arthritis, osteomyelitis, myositis, ear-nose-throat infections
Allergic disease: asthma, eczema, hay fever, food allergies
Oncologic disease
Cystic Fibrosis
Type 1 Diabetes Mellitus
Congenital metabolic disease
Undernutrition

Study design

Design

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

Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-02-2014
Enrollment:	420
Type:	Actual

Ethics review

Approved WMO Date:	11-12-2013
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	05-09-2016
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL43949.068.13
Other	Prevent CardioKids