Secondary prevention of asthma in overweight/obese children by a combined dietary-behavioural-physical activity intervention

Published: 16-11-2009
Last updated: 06-05-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Diabetic complications
Study type	Interventional

Summary

ID

NL-OMON36508

Source
ToetsingOnline

Brief title
Weight-reduction intervention in asthmatic children with overweight/obesity

Condition

- Diabetic complications
- Bronchial disorders (excl neoplasms)

Synonym
asthma bronchiale, corpulence

Research involving
Human

Sponsors and support

Primary sponsor: Research Institue CAPHRI, sectie kinderlongziekten
Source(s) of monetary or material Support: Nederlands Astmafonds

Intervention

Keyword: Asthma, Children, Intervention, Obesity

Outcome measures

Primary outcome

The FEV1% predicted value is the primary outcome measure.

Secondary outcome

The secondary outcome parameters are: body weight, length and BMI; static lung function; exacerbations/symptoms; asthma control; Quality of life; medication; non-invasive inflammatory markers and; serum adipokines, adiponectin and leptin concentrations.

Study description

Background summary

Overweight and obesity has reached epidemic proportions worldwide, with more than one billion adults overweight - at least 300 million of them clinically obese - and is a major contributor to the global burden of chronic disease and disability. Increased consumption of more energy-dense, nutrient-poor foods with high levels of sugar and saturated fats in combination with reduced physical activity, have led to obesity rates that have risen three-fold since 1980. In the Netherlands, overweight is present in 13% of the boys and 14% of girls. Previous research demonstrates an increased risk on the development of asthma in overweight children. Obesity is related to more severe asthma. In adults, there is evidence that interventions directed towards weight reduction and physical exercise are of help in improving asthma symptoms, exacerbation rate, lung function, and quality of life. Such studies have not been performed in children. Effective weight reduction programs have been reported in children.

Study objective

The current proposal studies the efficacy of a multifactorial intervention with weight reduction, behavioural therapy, and physical exercise on the severity and control of overweight/obese children with asthma.
Also the underlying mechanism of these interventions will be studied. In addition the maintenance of the treatment effect after the intervention is studied.

Study design

A two year, open randomized follow-up control trial.

Intervention

The control group (n=75) will receive standard usual care according to the standards of the Dutch Society of General Practitioners (NHG) and the Paediatric Pulmonology section of the Dutch Society of Paediatrics (NVK).

The intervention group (n=75) will be an active intervention group with a multifaceted family-based, physical exercise, nutrition, and behavioural intervention during 18 months.

Study burden and risks

The nature of the burden associated with participation consist of: the dietary intervention, physical exercise and the behavioural intervention. The baseline measurement and last visit (t=0 and t=18 months) includes: a venapunction, a static lung function test (also measured at t=6 months), collecting of exhaled breath condensate and filling in a quality of life questionnaire. The dynamic lung function test will be performed at 0, 6, 12, 18 and 24 months. Weight, heigth and BMI will be determined at the same moments. Every month the presence and severity of symptoms will be determined with a questionnaire.

Children receive a balanced hypocaloric diet for 18 months. At 0, 1, 3, 6, 12, and 18 months the subjects will visit a clinical dietician with paediatric experience. Every two weeks, parents and children will report two days of 24-hour intake of food and drinks.

The subjects will visit a research nurse with behavioural intervention experience at 0, 1, 3, 6, 12, and 18 months.

Children will attend the physical exercise program twice a week during the first six months (100 minutes per week) and every other week for an additional 12 months (100 minutes twice per month). Children are also encouraged to exercise 3 additional days at home per week. Children and parents will register

activities every two weeks in a diary.

There are no risks associated with participation. The intervention is non-invasive. Other study measures are also non-invasive, except the venapunction. The intervention could have beneficial effects for the study population, because an improving body weight/BMI and physical exercise in these obese children with asthma is expected, which probably will improve their health status, quality of life, asthma control, and need for medication.

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

- Children aged 6-16 years.

- A Body mass index (BMI) in the overweight/obesity range according to Cole et al.
- An asthma diagnosis of the general practitioner or with symptoms/medication suggestive for asthma

Exclusion criteria

- Children with a normal weight according to Cole et al.
- Children without any provable asthmatic complaints
- Congenital malformations of the airways or other chronic lung diseases like cystic fibrosis (CF)
- Mental retardation or syndromes
- Heart disease

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	17-05-2010
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO

Date:	16-11-2009

Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	30-05-2011
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
ClinicalTrials.gov	NCT00422747
CCMO	NL28214.068.09

Study results

Date completed:	07-11-2014
Actual enrolment:	86