The effect of weight loss through a low calory diet on exercise induced asthma in children with asthma and moderate overweight.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28255

Source
NTR

Brief title
EIB in overweight children

Health condition

Overweight and exercise induced asthma in children.
Dutch: Overgewicht en inspanningsastma bij kinderen.

Sponsors and support

Primary sponsor: Dr. B.J. Thio
Medisch Spectrum Twente
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Source(s) of monetary or material Support: Dr. B.J. Thio
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Intervention

Outcome measures

Primary outcome

Analyze the relation between the reduction in BMI and the reduction in exercise induced fall in FEV1, after a diet-period of 6 weeks.

We measure the exercise induced fall in FEV1 with an exercise provocation test before and after the diet.

Secondary outcome

Secondary we analyze the relation between reduction in BMI and the recovery of the lungfunction to baseline, the increase in baseline FEV1, the reduction in FeNO, quality of life and the asthma control.

Study description

Background summary

Previous studies in asthmatic obese children show a relation between obesity and bronchial hyperresponsiveness, a characteristic feature of asthma. Several underlying mechanisms have been suggested to explain the interaction between obesity and asthma. The effect of weight loss on BHR to an indirect stimulus has not yet been studied in adults or children. The aim of our study is to investigate the effect of weight loss through a low calory diet on EIB in children with asthma and moderate overweight. We expect losing weight will improve pulmonary function, decrease symptom scores and diminishes ΔFEV1 after exercise.

Study objective

Previous studies in asthmatic obese children show a relation between obesity and bronchial hyperresponsiveness, a characteristic feature of asthma. Several underlying mechanisms have been suggested to explain the interaction between obesity and asthma. The effect of weight loss on BHR to an indirect stimulus has not yet been studied in adults or children. The

aim of our study is to investigate the effect of weight loss through a low calory diet on EIB in children with asthma and moderate overweight. We expect losing weight will improve pulmonary function, decrease symptom scores and diminishes ΔFEV1 after exercise.

To analyze the relation between reduction in BMI and reduction in the exercise induced fall of FEV1 after a diet-period of 6 weeks. Secondary we analyze the relation between reduction in BMI and the recovery of the lungfunction to baseline (measured as total Area Under the Curve), the increase in baseline FEV1, the reduction in FeNO (measured with the miniNIOX®), quality of life (measured with the Pediatric Asthma Quality of Life Questionnaire) and the asthma control (measured with the Asthma Control Questionnaire).

Study design

The measurements will be done before and after the diet period of 6 weeks. Weight, height and bio-electric impedance will also be measured after 2 and 4 weeks.

To measure pulmonary volumes and flow-volume loops we use a MicroLoop spirometer in combination with Spida5 software.

The FENO we measure with the miniNOX.

The quality of life with the pediactric asthma quality of life questionnaire.

The asthma control with the asthma control questionnaire.

Intervention

All children will follow a low calory diet for 6 weeks in order to lose weight. After that period we measure the change in BMI.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age between 8-18 years;

2. Doctors diagnosis of mild to moderate asthma;

3. Exercise induced asthma defined by a >10% exercise induced fall in FEV1;

4. BMI score above or at the cut off points for overweight, based on international data and linked to the widely accepted adult cut off points of a body mass index of 25 kg/m2;

5. Clinically stable period at least 3 weeks before the study period;

6. Maximal FEV1 >70% of predicted value.

Exclusion criteria

1. Other pulmonary or cardiovascular illnesses;

2. Genetic disorders;

3. Maximal FEV1 <70% of predicted value;

4. Use of long acting bronchodilators 24 hours before testing;

5. Use of short acting bronchodilators 8 hours before testing.

Study design

Design

Study type: Interventional

Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	13-12-2010
Enrollment:	29
Type:	Anticipated

Ethics review

Positive opinion

Date:	29-11-2010
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 34483
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2513
NTR-old	NTR2631
CCMO	NL34595.044.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Register	ID
OMON	NL-OMON34483

Study results

Summary results
N/A