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

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28255

Bron
NTR

Verkorte titel
EIB in overweight children

Aandoening

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

Ondersteuning

Primaire sponsor: Dr. B.J. Thio
Medisch Spectrum Twente
Afdeling kindergeneeskunde
Haaksbergerstraat 55, 7513 ER Enschede
Postadres: Postbus 50.000, 7500 KA Enschede
Tel: (053)-4872310
Email: B.Thio@ziekenhuis-mst.nl

Overige ondersteuning: Dr. B.J. Thio
Medisch Spectrum Twente
Afdeling kindergeneeskunde
Haaksbergerstraat 55, 7513 ER Enschede
Postadres: Postbus 50.000, 7500 KA Enschede
Tel: (053)-4872310
Email: B.Thio@ziekenhuis-mst.nl

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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).

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

Postbus 50.000
Mira Hoogstrate
Medisch Spectrum Twente, Afdeling Kindergeneeskunde
Haaksbergerstraat 55
Enschede 7500 KA
The Netherlands
+31 (0)53 4872310

Wetenschappelijk

Postbus 50.000
Mira Hoogstrate
Medisch Spectrum Twente, Afdeling Kindergeneeskunde
Haaksbergerstraat 55
Enschede 7500 KA

The Netherlands
+31 (0)53 4872310

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	13-12-2010
Aantal proefpersonen:	29
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	29-11-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 34483
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2513
NTR-old	NTR2631

Register	ID
CCMO	NL34595.044.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON34483

Resultaten

Samenvatting resultaten
N/A