Exercise induced bronchoconstriction in 5 till 7 year old children with asthma.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25023

Source
NTR

Brief title
EIB 5-7

Health condition

-Asthma (astma)
-Exercise induced bronchoconstriction (inspanningsastma)

Sponsors and support

Primary sponsor: Stichting pediatrisch onderzoek Enschede, Medisch Spectrum Twente, Enschede
Source(s) of monetary or material Support: Stichting pediatrisch onderzoek Enschede

Intervention

Outcome measures

Primary outcome

Main objective of this study is the measurement of pulmonary function (change in FEV1, FEV0.5 and FEF50) during and post-exercise in young children with asthmatic features. Thus the percent change in pulmonary function (FEV1, FEV0.5 and FEF50) during and post-

exercise.

Secondary outcome

1. Analysis of anthropometric measures, clinical features, medication use and history (measured by extensive history) of children with a positive or negative exercise provocation challenge;

2. Analysis of the feasibility of a newly designed exercise provocation challenge using a jumping castle.

Study description

Background summary

N/A

Study objective

The aim of this study is to investigate the course of EIB in young asthmatic children, by using a newly designed exercise provocation challenge.

Study design

One visit.

Intervention

No intervention, other than the exercise provocation challenge, will be investigated. An exercise provocation challenge is part of the routine clinical evaluation of patients with exercise induced symptoms or asthma. However, an exercise provocation challenge in the evaluation of asthmatic children aged 5 till 7 years isn’t widely used and can therefore be seen as an intervention. Moreover, our newly designed exercise provocation challenge, using a jumping castle is experimental.
Thus the intervention used in our study is a newly designed exercise provocation challenge.

This exercise provocation challenge exists of jumping on a jumping castle for at least 4 minutes (target is a 6 minute lasting exercise at 80% of the predicted maximum heart rate). Before, during and after exercise, patients perform pulmonary function measurements (flow volume curves).

Contacts

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Eligibility criteria

Inclusion criteria

1. Clinical history of asthma symptoms;

2. Age 5 till 7 years;

3. Ability to perform reproducible lung function tests;

4. Clinically stable period at least 4 weeks before the study period (no hospital admission or use of systemic corticosteroids).

Exclusion criteria

1. Use of systemic corticosteroids in the last 4 weeks prior to the study;

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

3. Use of short acting bronchodilators 8 hours before testing;

4. Use of leukotriene antagonists 24 hours before testing;

5. Other pulmonary or cardiac disorder.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2011
Enrollment:	50
Type:	Anticipated

Ethics review

Positive opinion

Date:	24-08-2011
Application type:	First submission

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
NTR-new	NL2892
NTR-old	NTR3038
Other	METC : P11-29
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A