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

Published: 04-10-2011
Last updated: 30-04-2024

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

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Observational non invasive

Summary

ID

NL-OMON35678

Source
ToetsingOnline

Brief title
EIB in 5-7 year olds

Condition

- Bronchial disorders (excl neoplasms)

Synonym
exercise induced asthma, exercise induced bronchoconstriction

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: Stichting Pediatrisch Onderzoek Enschede

Intervention

Keyword: asthma, children, exercise induced bronchoconstriction, pulmonary function

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

Secondary objectives are:

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

-analysis of the feasibility of a newly designed exercise provocation challenge using a jumping castle.

Study description

Background summary

Exercise induced bronchoconstriction (EIB) is highly specific for asthma and exercise provocation challenges are therefore frequently used to diagnose asthma and evaluate asthma treatment. There seems to be an important relation between age and the clinical course of EIB; the younger the child, the shorter the time to maximal bronchoconstriction following exercise and the quicker the recovery from EIB. Moreover, in many asthmatic children EIB starts during, and not after, exercise. Little is known about the clinical course of EIB in young children (<8 years).

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

This study is of a cross-sectional, single occasion observational design. Patients will undergo an extensive evaluation of their asthma, including a history, physical examination and 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).

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).

Study burden and risks

The risks of participation are considered minimal.
Patients have to undergo one exercise provocation challenge with the chance of getting dyspnoeic. Especially in children, exercise limitation is a heavy burden on the quality of life, however the exercise challenges poses a minimal risk. The possible dyspnoea is comparable to that experienced when exercising in real life and children generally consider this as a minimal burden.
With the development of the design of our exercise provocation challenge, the age of the children is taken into consideration. We tried to minimize the burden of exercise by using a jumping castle.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

- Clinical history of asthma symptoms.
- Age 5-7 years.
- Ability to perform reproducible lung function tests, i.e. coefficient of the predicted value variation in 3 of 5 consecutive measurements < 5%.
- Clinically stable period at least 4 weeks before the study period (no hospital admission or use of systemic corticosteroids).

Exclusion criteria

- Use of systemic corticosteroids in the last 4 weeks prior to the study.
- Use of long acting bronchodilators 24 hours before testing.
- Use of short acting bronchodilators 8 hours before testing.
- Use of leukotriene antagonists 24 hours before testing.
- Other pulmonary or cardiac disorder.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	28-11-2011
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	04-10-2011
Application type:	First submission
Review commission:	METC Twente (Enschede)

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	NL38021.044.11

Register	ID
Other	NTR-volgt