Determination of exercised-induced bronchoconstriction with a standardized exercise test for infants and young children (3-6 years).

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To determine exercised-induced bronchoconstriction with an objective and standardized exercise test for infants and young children (3-6 years); to compare resistance and compliance in wheezy children and healthy children before and after exercise-...

Ethical review	Not approved
Status	Will not start
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Interventional

Summary

ID

NL-OMON31591

Source
ToetsingOnline

Brief title
Exercise testing in preschool children

Condition

- Bronchial disorders (excl neoplasms)

Synonym
childhood asthma, wheezing disorder in infants

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W,subsidieaanvraag bij Stichting Astmabestrijding

Intervention

Keyword: asthma, children, Exercise testing, forced oscillation technique

Outcome measures

Primary outcome

-Number of children with exercise-induced bronchoconstriction in the wheeze

group compared to the healthy group.

-Number of children with bronchoconstriction measured by FOT at 3-6 years of

age compared to number of children with bronchoconstriction measured with

treadmill/ histamine challenge at 7-8 years of age.

-Number of children able to perform the test at 3-6 years

-Reproducibility

Secondary outcome

not applicable

Study description

Background summary

Wheezy disorders are common and form a heterogeneous group. The majority of infants with wheeze do not have an increased risk of asthma later in life. Hence it would be important to distinguish between early transient, late-onset and persistent wheeze. The latter is associated with asthma and patients need treatment. Because these wheezy disorders are difficult to distinguish from each other clinically, it would be helpful to have some objective measures for diagnosis. Asthma has characteristic features such as reversible airway obstruction, bronchial hyperresponsiveness and airway inflammation. In older children and adults, bronchial hyperresponsiveness can be measured using pharmacological agents such as histamine or using exercise tests. Due to age dependent limitation of cooperation, lung function measurements and challenge

tests in preschool aged children are difficult to perform. Forced Oscillation Technique (FOT) measures resistance and reactance and has the potential to determine the presence of airway obstruction or hyper-reactivity.

Study objective

To determine exercised-induced bronchoconstriction with an objective and standardized exercise test for infants and young children (3-6 years); to compare resistance and compliance in wheezy children and healthy children before and after exercise-testing; to study whether young children with exercised-induced bronchoconstriction remain hyperreactive when they grow older.

Study design

prospective, observational study

Used methods:
-exercise test (free running)
-lung function test (forced oscillation technique)
-Exercise test (tread mill)
-Histamine challenge

Intervention

Exercise testing/ Histamine Challenge test

Study burden and risks

Children perform the test, which consists of 6 minutes free running, once. Lung function measurements are performed using forced oscillation technique before and after the running. Free running is a normal activity for children and risks are therefore low. Heart rate will be monitored during the test. In case of bronchoconstrition and no return to the baseline level, a short acting beta2 agonist will be given to reverse the bronchoconstriction. A document that has been developed by the ad hoc group for the development of implementing guidelines for Directive 2001/20/EC1 relating to good clinical practice in the conduct of clinical trials on medicinal products for human use, chaired by the European Commission considered spirometry to have no risk and exercise testing as minor increase above minimal risk.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Age: 3-6 years
-Asthma:
Children with episodic attacks (>3 times/year) of wheeze, shortness of breath or cough.
-Controls:
Healthy, no respiratory smptoms

Exclusion criteria

-recent respiratory infection,
-severe respiratory symptoms with need for oral steroids,
-history of prematurity and/or intensive care treatment,
-other respiratory disorders such as Cystic Fibrosis,
-other disorders that limit the possibily to perform an exercise test

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	100
Type:	Anticipated

Ethics review

Not approved

Date:	05-02-2009
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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	NL20182.000.08