The effect of exercise induced extra-thoracic airway obstruction on end expiratory lung volume in children.

Published: 30-06-2008
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Analyze the correlation between change in EELV with change in MIF50

Ethical review	Not approved
Status	Will not start
Health condition type	Upper respiratory tract disorders (excl infections)
Study type	Interventional

Summary

ID

NL-OMON32324

Source
ToetsingOnline

Brief title
EIET on EELV

Condition

- Upper respiratory tract disorders (excl infections)

Synonym
Exercise induced airway obstruction, Exercise induced asthma

Research involving
Human

Sponsors and support

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

Intervention

Keyword: children, End Expiratory lung Volume, Exercise induced airway obstruction, Extra-thoracic ariway obstruction

Outcome measures

Primary outcome

The study endpoint will be the end of the exercise provocation test, where

change in MIF50 will be linked to change in EELV.

Secondary outcome

not applicable

Study description

Background summary

Exercise induced airway obstruction (EIAO) is defined as an acute, reversible bronchial obstruction occurring immediately after and occasionally during physical exercise. EIAO is highly prevalent in adults and children with asthma and especially in childhood an invalidating entity. Besides wheezing as a sign of bronchial obstruction, exercise may induce an inspiratory stridor, suggesting an extra-thoracic airway obstruction. Extra-thoracic airway obstruction has been reported in response to pharmacological and physical challenges with or without bronchial obstruction. Extra-thoracic airway obstruction can be measured with a drop of more then 25% of the forced mid-inspiratory flow (MIF50).
In exercise, as the exercise load increases, tidal volume increases and end expiratory lung volume (EELV) decreases. Asthmatics, despite having end expiratory flow limitation do not show and increase in EELV. This may be due to inspiratory flow limitation, caused by extra-thoracic airway obstruction. The aim of the study is to investigate the effect of exercise induced extra-thoracic airway obstruction (EIET) on EELV in asthmatic and healthy children.

Study objective

Analyze the correlation between change in EELV with change in MIF50

Study design

This is a observational study design with a non-medicinal intervention

Intervention

2 exercise provocation tests.

Study burden and risks

Patients will have to undergo two subsequent exercise provocation challenges. These challenges will be in one session, which will take approximately 2 hours. Especially in children exercise limitation is a heavy burden on quality of life, however the exercise challenges pose a minimal risk. The possible dyspnoea is comparable to that experienced when exercising in real life.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)

Inclusion criteria

Inclusion criteria (asthmatic subjects)
- Clinical history of allergic rhinitis and/or allergic asthma.
- Age between 12 and 17 years.
- Ability to perform reproducible lung function tests, i.e. coefficient of the predicted value variation in 3 of 5 consecutive measurements < 5%.
- Maximal FEV1 greater than 70% of predicted value.
- Clinically stable period at least 3 weeks before the study period. ;Inclusion criteria (healthy subjects)
- No currently reported illnesses.
- Age between 12 and 17 years.
- Ability to perform reproducible lung function tests, i.e. coefficient of the predicted value variation in 3 of 5 consecutive measurements < 5%.
- Maximal FEV1 greater than 70% of predicted value.
- Clinically stable period at least 3 weeks before the study period.

Exclusion criteria

Exclusion criteria (asthmatic subjects)
- Use of intranasal or systemic corticosteroids in the last 4 weeks prior to the study.
- Use of antihistamines, cromoglycates, anticholinergics in two weeks prior to the study.
- Use of long acting bronchodilators 24 hours before testing.
- Use of short acting bronchodilators 8 hours before testing.
- Other pulmonary or cardiac disorder.
- Deviation of the FEV1 of more than 12 % from baseline spirometry and the FEV1 before subsequent exercise provocation challenges.
- Signs of gastro-esophageal reflux. ;Exclusion criteria (healthy subjects)
- Reported Illness in the past.
- Exhaled NO of more than 20 ppb
- Signs of gastro-esophageal reflux.

Study design

Design

Study type: Interventional

Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	0
Type:	Anticipated

Ethics review

Not approved

Date:	30-06-2008
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	NL20789.000.07