The protective effect of levocetirizine on exercise induced airway obstruction in cold air.

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Analyze the protective effect of levocetirizine (LEV), through the direct antagonism of airway H1 receptors and the inhibition of the release or production of other inflammatory mediators, against exercise induced airway obstruction.

Ethical review	Not approved
Status	Will not start
Health condition type	Respiratory disorders NEC
Study type	Interventional

Summary

ID

NL-OMON32040

Source
ToetsingOnline

Brief title
icetrackstudy

Condition

- Respiratory disorders NEC

Synonym
exercise induced airway obstruction

Research involving
Human

Sponsors and support

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

Intervention

Keyword: airway obstruction, levocetirizine

Outcome measures

Primary outcome

The reduction in exercise induced fall of FEV1, MIF50 and increase in airway

resistance after a single dose of LEV.

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. EIAO is considered to be a manifestation of airway hyperresponsiveness and highly specific for asthma in children.
The exact mechanism of exercise induced bronchial obstruction (EIB) is not known, however, two hypotheses have been proposed. Besides wheezing as a sign of bronchial obstruction exercise may induce an inspiratory stridor, suggesting an extra-thoracic airway obstruction.
Asthma and allergic rhinitis commonly coexist with histamine as a common mediator. Antihistamines are widely used in the treatment of allergic rhinitis. Histamine and other inflammatory mediators have been suggested to be involved in EIB. However, pretreatment with specific H1-receptor antagonists has given variable results. The effect of antihistamines on exercise induced extra-thoracic airway obstruction (EIET) has not yet been studied.
The aim of the study is to investigate whether levocetirizine (LEV) protects against airway obstruction after exercise.

Study objective

Analyze the protective effect of levocetirizine (LEV), through the direct antagonism of airway H1 receptors and the inhibition of the release or production of other inflammatory mediators, against exercise induced airway

obstruction.

Study design

This is an interventional-observational study

Intervention

Participants will receive a single dose of 5 mg LEV or placebo 4 hours prior to performing an exercise challenge test. A week later they will receive the opposed treatment.

Study burden and risks

Patients will have to undergo three exercise provocation challenges. Each of these tests takes about 2 hours, for a total load of 6 hours. Especially in children exercise limitation is a heavy burden on quality of life, however the exercise challenges poses 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

- 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.

Exclusion criteria

- 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 intranasal or systemic corticosteroids, antihistamines, cromoglycates, anticholinergics, during 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.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo

Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	24
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Xyzal
Generic name:	Levocetirizine
Registration:	Yes - NL outside intended use

Ethics review

Not approved

Date:	29-07-2008
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
EudraCT	EUCTR2007-005928-33-NL
CCMO	NL21454.000.08