The protective effect of a nasal steroid (Fluticasone furoate) on exercise induced airway obstruction in cold air.

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Analyze the protective effect of intranasal corticosteroids against exercise induced upper and lower airway obstruction

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

Summary

ID

NL-OMON31652

Source
ToetsingOnline

Brief title
Icehall Studie

Condition

- Respiratory disorders NEC

Synonym
Exercise induced Airway obstruction, Laryngeal hyperreactivity

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: Schering-Plough,Stichting pediatrich onderzoek Enschede

Intervention

Keyword: Asthma, Children, exercise induced airway obstruction, nasal steroid

Outcome measures

Primary outcome

Cold air exercise provocation test. Lungfunction will be determined with

spirometric and oscillometric measurements.

Secondary outcome

Asthma Controle Questionnaire by Juniper

Borg scale of dyspneoa

Study description

Background summary

Dyspnoea cause by exercise is a common problem in children with astma and is a sign of airway hyperreactivity. Dyspnoea due to exercise is the most common complaint in children with asthma. Exercise induced airway obstruction can occur intra- and extra-thoracic.
Hyperreactivity in the upper airways is often the cause of allergic rhinitis or gatro-oesophagal reflux. Hyperreactivity in the upper airways can be diminished with a nasal steroid.

Study objective

Analyze the protective effect of intranasal corticosteroids against exercise induced upper and lower airway obstruction

Study design

Children with exercise induced airway obstruction will continue in the study of a double-blind, randomized, and placebo-controlled design. Children will receive placebo or 27,5 *g Fluticasone furoatein each nostril for 4 weeks.

Intervention

Children will receive placebo or 27,5 *g Fluticasone furoate in each nostril for 4 weeks.

Study burden and risks

The risk for patients has been estimated to be negligible.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

children (12-17 years) with a history allergic rhinitis and/or allergic asthma
able to perform lung-function
FEV1>70% of predicted

clinically stable for 3 weeks

Exclusion criteria

Use of nasal/systemic steroids
bronchodilators prior to test
other cardiac or pulmonary disease
signs of gastro-oesophagal reflux

Study design

Design

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	91
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Brand name:	Avamys
Generic name:	Fluticasone furoate
Registration:	Yes - NL intended use

Ethics review

Not available

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	EUCTR2006-005875-16-NL
CCMO	NL15101.044.06