The protective effect of azelastine/fluticasone propionate (Dymista) on exercise-induced airway obstruction

Published: 11-12-2018
Last updated: 21-09-2024

To analyze the protective effect of azelastine/fluticasone propionate against exercise-induced airway narrowing by measuring inspiratory and expiratory airflow limitation and airway resistance and reactance in asthmatic children.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON48838

Source
ToetsingOnline

Brief title
Protective effect of DYM on EIAO

Condition

- Other condition
- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
asthma, exercise-induced asthma

Health condition

bovenste luchtwegaandoeningen, allergische rhinitis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Allergic rhinitis, Asthma, Exercise-induced asthma, Intranasal corticosteroids

Outcome measures

Primary outcome

-Analyze the reduction in exercise-induced fall in FEV1 after three weeks of treatment with azelastine/fluticasone propionate in comparison with a placebo.

-Analyze the reduction in exercise-induced fall in MIF50 after three weeks of treatment with azelastine/fluticasone propionate in comparison with a placebo.

Secondary outcome

-Analyze the reduction in exercise-induced increase of airway resistance at low frequency, measured with FOT, after three weeks of treatment with azelastine/fluticasone propionate in comparison with a placebo.

-Analyze the reduction in exercise-induced decrease of airway reactance at low frequency, measured with FOT, after three weeks of treatment with azelastine/fluticasone propionate in comparison with a placebo.

-Analyze the increase in quality of life, measured with the pediatric asthma quality of life questionnaire (PAQLQ), after three weeks of treatment with azelastine/fluticasone propionate in comparison with a placebo.

-Analyze the increase in control of asthma, measured with the asthma control test (ACT), after three weeks of treatment with azelastine/fluticasone

propionate in comparison with a placebo

Study description

Background summary

Exercise-induced airway obstruction (EIAO) is an acute, reversible bronchial obstruction occurring after of during physical exercise (1). It classically limits expiratory airflow and is then referred to as exercise-induced bronchoconstriction (EIB). However, to a certain degree most children also display inspiratory airflow limitation. EIAO is highly prevalent in children with asthma and a frustrating morbidity. It reflects active inflammation of the airways and is a sign of uncontrolled asthma. It is associated with atopy and considered to be a manifestation of airway hyperresponsiveness (AHR). AHR is the term commonly used to identify how fast and to which degree airway obstruction occurs due to a variety of stimuli, such as exercise.
Allergic rhinitis is a frequent co-morbidity of childhood asthma and an uncontrolled allergic rhinitis can deteriorate existing pulmonary problems. Intra-nasal corticosteroids are effective against allergic rhinitis and reduce EIB in asthmatic children. The exact mechanisms underlying the effect of nasal steroids on EIB are unclear. In this study, we want to investigate the potential effect of azelastine/fluticasone proprionate against exercise-induced changes in asthmatic children.

Study objective

To analyze the protective effect of azelastine/fluticasone propionate against exercise-induced airway narrowing by measuring inspiratory and expiratory airflow limitation and airway resistance and reactance in asthmatic children.

Study design

This prospective study is of a double-blind, randomized, and placebo-controlled design.

To increase the power for the interim analysis, 10 patients will be included in the Dymista group. These patients will receive the same information as the other patients, namely that they participate in an RCT and can receive either Dymista or a placebo, thereby influencing these 10 tests as little as possible. The long function physician that performs these tests is also not informed that these 10 patients all receive Dymista (and not a placebo) to influence these tests as little as possible.

Intervention

Participants in the intervention group will receive 1 puff azelastine/fluticasone propionate twice a day in each nostril. Participants in the control group will receive a placebo.

Study burden and risks

Patients will undergo two ECT*s. Each of these tests takes about 1 hour, for a total load of 2 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 daily 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 EIB
- Age between 12 and 18 years.
- Ability to perform spirometry and FOT

Exclusion criteria

- Other pulmonary or cardiac illnesses
- Severe EIB i.e. a fall of >=40% FEV1 in the first ECT, requiring an acute change in maintenance medication (standard care)
- Use of long acting bronchodilator agents 24 hours before testing
- Use of short acting bronchodilator agents 8 hours before testing
- Hospitalization due to asthma exacerbation in the last 4 weeks
- Use of intranasal or systemic corticosteroids in the last 4 weeks prior to the study.
- Use of antihistamines, cromoglycates, anticholinergics in two weeks prior the study or during the study.
- Other changes in asthma medication during treatment period
- Insufficient knowledge of the Dutch language

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:	Recruiting
Start date (anticipated):	15-04-2019

Enrollment:	41
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Dymista
Generic name:	Azelastine hydrochloride and fluticasone propionate
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	11-12-2018
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	17-01-2019
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	28-03-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	31-07-2019
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	13-09-2024
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	EUCTR2018-001120-18-NL
CCMO	NL65451.044.18