The protective effect of Dymista on exercise-induced asthma

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We expect that treatment with azelastine/fluticasone propionate will decrease exercise tolerance limitation and will improve quality of life.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20219

Bron
NTR

Verkorte titel
DYM

Aandoening

Astma
Inspanningsastma
Dymista
Allergische rhinitis

Asthma
Exercise-induced asthma
Dymista
Allergic rhinitis

Ondersteuning

Primaire sponsor: Stichting Pediatrisch Onderzoek Enschede
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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- Het analyseren van de reductie van inspanningsgeïnduceerde daling in FEV1 na 3 weken behandeld te zijn met
azelastine/fluticason proprionaat, in vergelijking met een placebo
- Het analyseren van de reductie van inspanningsgeïnduceerde d aling in MIF50 na 3 weken behandeld te zijn met
azelastine/fluticason proprionaat, in vergelijking met een placebo

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:

Exercise-induced airway obstruction (EIAO) is an acute, reversible bronchial obstruction occurring after of during physical exercise. 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 mechanisms of the protection of azelastine/fluticasone proprionate against exercise-induced changes in airway physiology in asthmatic children.

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.

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

Study population: 64 children with a history of allergic rhinitis and EIB between 12-18 years will be included from the outpatient clinic of the pediatric departments of Medisch Spectrum Twente in Enschede.

Intervention (if applicable): 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.
Main study parameters/endpoints: The reduction in exercise-induced fall in FEV1 (forced expiratory volume in 1 second) and MIF50 (maximal inspiratory flow at 50% of the vital capacity) and exercise-induced increase in resistance and reactance as measured with forced oscillation technique (FOT) during a ECT (exercise challenge test) after three weeks of treatment with azelastine/fluticasone propionate.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: 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 dyspnea is comparable to that experienced when exercising in daily life.

Doel van het onderzoek

We expect that treatment with azelastine/fluticasone propionate will decrease exercise tolerance limitation and will improve quality of life.

Onderzoeksopzet

- De eerste inspanningstest bij start van de studie

- Een tweede inspanningstest aan het einde van de studie, na een behandeltijd van 3 weken

Onderzoeksproduct en/of interventie

During their first visit, children will fill out the ACT (14) and PAQLQ (15) and demographic data on age, sex and
body mass index (BMI) will be noted. Lung function will be assessed with spirometry during a standard ECT
(jumping castle or treadmill, depending upon the preference of the child with regard to age) and with FOT. Children
with EIB will continue with the study and will be randomized in either the placebo group or the intervention group,
stratified on the use of inhaled corticosteroids (ICS) and fall in FEV1 (¡Ü25% and >25%).

The participants in the intervention group will receive 1 puff azelastine/fluticasone propio nate137/50 ¦Ìg twice a
day in each nostril, the control group will receive a placebo. After the trial period of 3 weeks, the participants will
again fill out the ACT and PAQLQ and perform the second ECT.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Clinical history of allergic rhinitis and EIB

- Age between 12 and 18 years

- Ability to perform spirometry and FOT

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Other pulmonary or cardiac illnesses

- Severe EIB i.e. a fall of ¡Ý40% 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.

- Insufficient knowledge of the Dutch language

Onderzoeksopzet

Opzet

Type: Interventie onderzoek

Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-11-2018
Aantal proefpersonen:	64
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7352
NTR-old	NTR7560
Ander register	METC Twente : P18-23

Resultaten