The predictive value of the acute effect of beclomethasone-dipropionate on an exercise-challenge test for the outcome of longterm treatment with beclomethasone-dipropionate in childhood asthma.

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Interventional

Summary

ID

NL-OMON47635

Source
ToetsingOnline

Brief title
Predictive value of single dose ICS

Condition

- Bronchial disorders (excl neoplasms)

Synonym
exercise induced bronchoconstriction

Research involving

Human

Sponsors and support

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

Intervention

Keyword: asthma, bronchial hyperresponsiveness, exercise-challenge test, inhaled corticosteroid

Outcome measures

Primary outcome

Correlation between the difference in fall in FEV1 after a single dose of Qvar

and after 4 weeks of treatment with Qvar.

Secondary outcome

na

Study description

Background summary

Asthma is a heterogeneous disease and clinical phenotypes are highly variable. This is exemplified in the variability of patients* responses to medications such as Qvar. It is a critical clinical question whether a particular therapy will be effective in an individual child with symptoms of asthma. At the moment, there is a lack of diagnostic tools to assess this individual responsiveness.
Qvar is an inhaled corticosteroid (ICS) used as controller therapy in children with asthma, providing protection against bronchial hyperresponsiveness (BHR) and exercise induced bronchoconstriction (EIB). A single dose of an ICS can have a significant effect on BHR measured by a bronchial provocation test (BPT). This rapid response shows variability similar to the variable responsiveness to long term treatment. We hypothesized that the effect of a single dose of Qvar on a BPT (an exercise-challenge test) could predict the effect of longterm therapy with Qvar on BHR.

Study objective

This study aims to investigate if there is a correlation between the severity of bronchoconstriction after an exercise challenge test 6h after a single dose of Qvar and after 4 weeks of treatment with Qvar, in order to know if the respons to a single dose of Qvar can predict individual response on the longer term.What

Study design

This study is of a prospective, open-label design.

Intervention

All children are treated with Qvar 100µg twice daily for 4 weeks.

Study burden and risks

This study is conducted in children because the burden of EIB is large in childhood and there are substantial differences in the pathofysiology of EIB between adults and children. Children more often perform spontaneous exercise and therefore do not always use prophylactic inhalation therapy.
Prophylactic maintenance therapy is therefore more widely used in children than in adults. We expect treatment with Qvar will improve pulmonary function, decrease symptom scores and diminish bronchial hyperresponsiveness. Side effects of Qvar are usually mild. Children will fill in an Asthma Control Test and will perform 2 exercise challenge tests. An exercise challenge test can cause dyspnea, for which Salbutamol will be given. The amount of dyspnea is comparable with the dyspnea that children experience during daily exercise. In general, children don't experience the exercise challenge tests as strenuous.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

- Age between 12-18 years
- Clinical history of asthma and exercise induced bronchoconstriction
- Ability to perform an exercise-challenge test
- Maximal FEV1 > 70% of predicted value

Exclusion criteria

- Other pulmonary or cardiac illnesses
- Use of nasal or systemic or inhalation corticosteroids, antihistamines, cromoglycates, anticholinergics or leukotriene
antagonists in two weeks prior to or during the study
- 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 past month
- Other changes in asthma medication during treatment period
- Upper or lower respiratory tract infections during treatment period
- Severe EIB i.e. a fall of >=40% FEV1 in the first ECT, requiring an acute change in maintenance medication
(standard care)
- Insufficient knowledge of the Dutch language

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-11-2016
Enrollment:	25
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Qvar
Generic name:	Beclomethasone diproprionate
Registration:	Yes - NL intended use

Ethics review

Approved WMO Date:	14-07-2016
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	04-08-2016
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	02-08-2017
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	29-07-2019
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	EUCTR2016-002276-27-NL
CCMO	NL58024.044.16
Other	trial register, nummer volgt