The predictive value of the acute effect of beclomethasone on a mannitol challenge test for the outcome of longterm treatment with beclomethasone

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What is the correlation between change in Mannitol PD15 (provoking dose of mannitol to cause a >= 15% fall in FEV1) 6h after a single dose of beclomethasone and after 4 weeks of treatment with beclomethasone?

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

Summary

ID

NL-OMON38395

Source
ToetsingOnline

Brief title
SD-QVAR

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 induced bronchoconstriction, inhaled corticosteroid

Outcome measures

Primary outcome

Correlation between change in Mannitol PD15 after a single dose of

beclomethasone and after 4 weeks of treatment with beclomethasone.

Secondary outcome

Which individual patient and disease characteristics are confounders for this

correlation?

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 beclomethasone. 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.
Beclomethasone 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 beclomethasone on a BPT (a mannitol challenge) could predict the effect of longterm therapy with beclomethasone on BHR.

Study objective

What is the correlation between change in Mannitol PD15 (provoking dose of mannitol to cause a >= 15% fall in FEV1) 6h after a single dose of beclomethasone and after 4 weeks of treatment with beclomethasone?

Study design

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

Intervention

All children are treated with beclomethasone 100µg or 200µg twice daily for 4 weeks.

Study burden and risks

Mannitol can mimic the airway response to exercise by influencing the osmolarity of the airway surface liquid and is used as an indirect BPT to diagnose and monitor BHR to exercise (EIB). EIB occurs in the majority of asthmatic children and has a great influence on their quality of life.1 Adults usually perform planned exercise and can take a short acting bronchodilator agent as prophylaxis. 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.2
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.2,3
We expect treatment with beclomethasone will improve pulmonary function, decrease symptom scores and diminish bronchial hyperresponsiveness. Side effects of beclomethasone are usually mild. Children will perform an Asthma Control Questionnaire and 3 mannitol challenges. A mannitol challenge can cause some dyspnoea, but ends when a >15% fall in FEV1 occurs. Furthermore, a mannitol challenge can cause some transient coughing.

Contacts

Public
Medisch Spectrum Twente

haaksbergerstraat 55
Enschede 7500KA
NL
Scientific
Medisch Spectrum Twente

haaksbergerstraat 55
Enschede 7500KA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Age between 12-18 years
- Clinical history of allergic asthma and exercise induced bronchoconstriction
- Ability to perform reproducible lung function tests (predicted value variation in 3 of 5 consecutive measurements < 5%)
- Maximal FEV1 > 70% of predicted value

Exclusion criteria

- Other pulmonary or cardiac illnesses
- Maximal FEV1 < 70% of predicted value
- Use of nasal or systemic 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
- Deviation of the FEV1 before the subsequent mannitol challenges of more than 12 % from baseline FEV1

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-07-2010
Enrollment:	19
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Osmohale
Generic name:	Mannitol
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	Qvar
Generic name:	beclomethasone diproprionate
Registration:	Yes - NL intended use

Ethics review

Approved WMO

Date:	23-04-2010
Application type:	First submission

Review commission:	METC Twente (Enschede)
Approved WMO Date:	31-05-2010
Application type:	First submission
Review commission:	METC Twente (Enschede)
Approved WMO Date:	21-06-2012
Application type:	Amendment
Review commission:	METC Twente (Enschede)

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	EUCTR2010-018937-23-NL
CCMO	NL31940.044.10