The predictive value of a single dose of beclomethasone.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24820

Source
NTR

Brief title
SD QVAR

Health condition

asthma
bronchial hyperresponsiveness
exercise induced asthma

Sponsors and support

Primary sponsor: Medisch Spectrum Twente, Enschede, the Netherlands
Source(s) of monetary or material Support: fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

The correlation between the effect of a single dose of beclomethasone on a mannitol challenge and the effect of 4 weeks of treatment on a mannitol challenge.

Secondary outcome

There will be tested for confounders for this correlation, such as age, gender and baseline lungfunction.

Study description

Background summary

Background:

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.

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.

Study population:

Children aged 12-18 years with a history of allergic asthma and BHR to exercise (EIB) who are started on beclomethasone for clinical reasons are asked to participate in this study.

Intervention:

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

Primary study parameters/outcome of the study:
Correlation between change in Mannitol PD15 after a single dose of beclomethasone and after 4 weeks of treatment with beclomethasone.

Secundary study parameters/outcome of the study:

Which individual patient and disease characteristics are confounders for this correlation?

Study objective

Most medications prescribed for the treatment of asthma have a variable responsiveness. It is clinically relevant to be able to predict responsiveness to a specific medicine in an individual patient. There is no such test currently available. Beclomethasone is one of the medications that has a variable responsiveness. Beclomethasone also has an acute effect on bronchial hyperresponsiveness and exercise induced bronchoconstriction. We hypothesize that the acute response to a single dose of beclomethasone could predict the response to long term treatment with beclomethasone.

Study design

1. Week 0: Inclusion, first mannitol challenge;

2. Week 1: Single dose, second mannitol challenges;

3. Week 2-5: 4 weeks of treatment with beclomethason;

4. Week 5: Third mannitol challenge.

Intervention

A single shot (200µg) of beclomethasone and 4 weeks of treatment with beclomethasone, 200µg twice daily.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age between 12-18 years;

2. Clinical history of allergic asthma and exercise induced bronchoconstriction;

3. Ability to perform reproducible lung function tests (predicted value variation in 3 of 5 consecutive measurements < 5%);

4. Maximal FEV1 > 70% of predicted value.

Exclusion criteria

1. Other pulmonary or cardiac illnesses;

2. Maximal FEV1 < 70% of predicted value;

3. Use of nasal or systemic corticosteroids, antihistamines, cromoglycates, anticholinergics or leukotriene antagonists in two weeks prior to or during the study;

4. Use of long acting bronchodilator agents 24 hours before testing;

5. Use of short acting bronchodilator agents 8 hours before testing;

6. Hospitalization due to asthma exacerbation in past month;

7. Other changes in asthma medication during treatment period;

8. Upper or lower respiratory tract infections during treatment period;

9. Deviation of the FEV1 before the subsequent mannitol challenges of more than 12 % from baseline FEV1.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2010
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	30-03-2010
Application type:	First submission

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
NTR-new	NL2142
NTR-old	NTR2266
Other	METC Medisch Spectrum Twente : P10-014
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A