

The predictive value of a single dose of beclomethasone.

Gepubliceerd: 30-03-2010 Laatste bijgewerkt: 18-08-2022

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....

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24820

Bron

NTR

Verkorte titel

SD QVAR

Aandoening

asthma
bronchial hyperresponsiveness
exercise induced asthma

Ondersteuning

Primaire sponsor: Medisch Spectrum Twente, Enschede, the Netherlands

Overige ondersteuning: fund = initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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 $\geq 15\%$ 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.

Secondary study parameters/outcome of the study:

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

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-05-2010
Aantal proefpersonen:	20
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	30-03-2010
Soort:	Eerste indiening

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

Resultaten

Samenvatting resultaten

N/A