Evaluation of the influence of particle size of aerosolized AMP on bronchial responsiveness in patients with asthma and the effects of treatment with ciclesonide versus fluticasone (protocol BY9010/NL101).

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The aim of this study is to investigate airway responsiveness to increasing doses of large particle and small particle aerosolized AMP and the changes in responsiveness to both challenges after treatment with ciclesonide in comparison with...

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

Samenvatting

ID

NL-OMON29179

Bron
NTR

Verkorte titel
BY9010/NL101 study

Aandoening

- To evaluate the effects of particle size of aerosolized AMP on the bronchial responsiveness in asthma
- To evaluate the effects of ciclsonide vs. fluticasone on large and small particle PC20 AMP

Ondersteuning

Primaire sponsor: ALTANA Pharma B.V, Hoofddorp, the Netherlands
Overige ondersteuning: ALTANA Pharma B.V, Hoofddorp, the Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To evaluate the effects of particle size of aerosolized AMP on the bronchial responsiveness in asthma.

Toelichting onderzoek

Achtergrond van het onderzoek

The study consists of a 5-week baseline period and a 5-week treatment period. At B0 inhaled glucocorticosteroid and long-acting beta-agonists will be withdrawn, if applicable, and will be replaced with a 5-week baseline treatment with fluticasone 100 µg b.i.d. and salbutamol as needed only. Steroid naive patients will also receive baseline treatment with fluticaseone 100 µg b.i.d. Patients showing bronchial hyperresponsiveness to AMP-ATS at B1 (PC20 ≤ 160 mg/ml) after 4 weeks treatment with fluticasone will be eligible to continue with this study. After the 5-week baseline period patients will be randomized to receive either 160 µg ciclesonide (ex-actuator) once daily in the morning or continue fluticasone 100 µg twice daily for 5 weeks. The entire treatment period will be conducted in a double-blind, double-dummy, randomized, parallel-group design.

Doel van het onderzoek

The aim of this study is to investigate airway responsiveness to increasing doses of large particle and small particle aerosolized AMP and the changes in responsiveness to both challenges after treatment with ciclesonide in comparison with fluticasone.

Onderzoeksproduct en/of interventie

The study is set up as a randomised, double-blind, dubbeldummy study in two parallel groups.
In period 1 (5 weeks) all the patients get an inhaler with Ventolin® which they can use during both study periods whenever they need to, but not for 6 hour priors to a visit. The patient will take 1 puff of 100 µg fluticasone twice daily in the morning and evening.
After five weeks (during the 4th visit in period 1) the investigator will select the patients that fulfill the inclusion criteria for period 2.
Period 2 (5 weeks) begins during the last visit of period 1. Patients will randomly be assigned to one of two treatment groups: group 1 receives ciclesonide 160 µg in the morning, and a placebo twice daily, group 2 receives fluticasone 100 µg twice daily and a placebo in the morning.

Then all the patients receive 4 inhalers (2 DPIs (dry powder inhalers) and 2 dose aerosols) for a period of 5 weeks. The patient takes 1 puff from DPI No. I twice daily and 1 puff from dose aerosol No. I in the morning. After thirty days, DPI No. 1 will be empty and the patient replaces both inhalers with the unused DPI inhaler No. II and dose aerosol No. II.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Written informed consent;
2. Outpatients males or females;
3. Good health with the exception of asthma;
4. Age 18 up to and including 60 years;
5. History of bronchial asthma (according to GINA 2004);
6. FEV1 > 1.20L, measured at least 6 hours after the last use of rescue medication;
7. Atopy shown by positive skin prick test to common allergen (historic tests are accepted, if results are available and test was done within 3 years prior to visit B0);
8. Stable asthma (no exacerbation or relevant respiratory tract infection within 2 months

prior to the study);
9. Patients who are steroid-naive or who have been pretreated with inhaled glucocorticosteroid of up to 500 µg/d fluticasone or equivalent alone or in combination with long-acting beta-agonists at a constant dosage for at least 28 days prior to visit B0.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

The presence of any one of the following will cause exclusion of the patient:
a. Diseases and health status:
1. Clinically relevant abnormal laboratory values suggesting an unknown disease and requiring further clinical evaluation;
2. Concomitant severe diseases, diseases expected to interfere with the outcome of the study and diseases which are contra-indications for the use of inhaled steroids (e.g. active or inactive pulmonary tuberculosis or relevant fungal, bacterial or viral infections of the lower respiratory tract demanding specific treatment);
3. Suffering from COPD (i.e. chronic bronchitis or emphysema) and/or other relevant lung diseases causing alternating impairment in lung function;
4. Hospitalization because of asthma during the previous 6 months prior to visit B0;
5. One asthma exacerbation within 2 months or more than 3 exacerbations within the last year prior to visit B0;
6. Ex-smokers with > 10 pack years, or having smoked within 1 year prior to visit B0;
7. Current smokers;
8. Positive response to saline challenge at baseline visits B1, B2 or B3 (defined as 20% fall in FEV1);
9. PC20 > 160 mg/ml to AMP-ATS at B1;
10. FEV1 ≤ 1.20 l prior to each bronchial challenge test;

b. Medications:
11. Use of systemic steroids within 4 weeks (injectable depot steroids 6 weeks) prior to visit B0 or more than 1 course during the last 6 months prior to visit B0;
12. Use of other drugs not allowed (see 7.4);
13. Washout times of drugs defined under 7.4 cannot be adhered to;
14. Known or suspected hypersensitivity to inhaled steroids or to the other excipients of the inhalatio devices;
15. Intolerance to salbutamol and excipients;
16. Beginning of immunotherapy during the patient's participation in the study or having begun an immunotherapy less than 3 months prior to visit B0 or alternation i regimen of an immunotherapy during the study period;

c. Common criteria:
17. Pregnancy;
18. Intention to become pregnant during the course of the study;
19. Breast feeding;
20. Lack of safe contraception:

Safe contraception is defined as follows:
female patients of childbearing potential not using and not willing to continue using a medically reliable method of contraception for the entire study duration such as oral, injectable or implantable contraceptives or intrauterine contraceptive devices unless they are surgically sterilized/hysterectomized or post-menopausal > 1 year or who are not using any other method considered sufficiently reliable by the investigator in individual cases;
21. Participation in another study within the 30 days preceding and during the present study;
22. Previous enrollment into the current study;
23. Enrollment of the investigator, his/her family members, employeees and other dependent persons;
24. Known or suspected non-compliance, alcohol or drug abuse;
25. Inability to follow the procedures of the study, e.g. due to language problems, psychological disorders;
26. Reversal of sleep pattern (e.g. night shift workers).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-04-2006
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	22-06-2006
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	NL650
NTR-old	NTR711
Ander register	: N/A
ISRCTN	ISRCTN37115189

Resultaten

Samenvatting resultaten

Cohen J et al. (2005): Relationship between airway responsiveness to eurokinin A and methacholine in asthma. Pulm Pharmacol Ther 2005; 18(3): 171-6. Epub 2005 Jan 22.

Crimi N et al. (2003): Inhibitory effect of a leukotriene receptor antagonist (montelukast) on neurokinin A-induced bronchoconstriction. J Allergy Clin Immunol. 2003 Apr; 111(4): 833-9.

O'Connor BJ et al. (2002a): Management of moderate to severe bronchial asthma by ciclesonide: a 12-week trial, ATS 2002

O'Connor BJ et al. (2002b): Treatment of moderate to severe asthma with ciclesonide: a long-term investigation over 52 weeks, ERS 2002.

Drollmann A et al. (2002): Ciclesonide shows high lung function deposition in 2D and 3D imaging, ATS 2002