Validation study to explore potential outcome parameters for a study with anti-IL-13 in allergic syndrome/asthma.

Gepubliceerd: 13-09-2005 Laatst bijgewerkt: 18-08-2022

Primary study objectives: 1. To test the reproducibility, in atopic subjects with a clinically stable allergic rhinitis, of: a. SPT; b. Relevant markers of allergic rhinitis and atopy in peripheral blood; 2. To validate the following assays...

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

Samenvatting

ID

NL-OMON26418

Bron
NTR

Verkorte titel
N/A

Ondersteuning

Primaire sponsor: C. Cusumano
Centocor Inc
200 Great Valley Parkway
19355-1307 Malvern
Pennsylvania USA
Tel: 00 1 610 2408475
Overige ondersteuning: Van Centocor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Primary study objectives:
1. To test the reproducibility, in atopic subjects with a clinically stable allergic rhinitis, of:

a. SPT;
b. Relevant markers of allergic rhinitis and atopy in peripheral blood;

2. To validate the following assays for measuring relevant biomarkers in atopic subjects with a clinically stable allergic rhinitis:
a. Exhaled nasal air;
b. Peripheral blood;
c. Nasal lavage;
d. Nasal brush.

Toelichting onderzoek

Achtergrond van het onderzoek

To investigate the role of mediators and cytokines in the pathophysiology of asthma and atopy, potent (specific) antagonists are the preferential tools. In this pilot study, we intend to validate potential outcome parameters and assays for a future study with anti-IL13 compounds. To this end, we intend to validate the reproducibility of skin prick tests (SPT), IgE, and several surrogate markers of allergic inflammation.

Doel van het onderzoek

Primary study objectives:

1. To test the reproducibility, in atopic subjects with a clinically stable allergic rhinitis, of:

a. SPT;

b. Relevant markers of allergic rhinitis and atopy in peripheral blood;

2. To validate the following assays for measuring relevant biomarkers in atopic subjects with a clinically stable allergic rhinitis:

a. Exhaled nasal air;

b. Peripheral blood;

c. Nasal lavage;

d. Nasal brush.

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

Subjects underwent a nasal allergen challenge with a relevant allergen according.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Male or female subjects;

2. 18-50 years of age with atopic rhinitis.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Current smokers (<6 months stopped) or ex-smokers (>10 packyears);

2. Any clinically significant deviation from normal in either the general physical examination or laboratory parameters as evaluated by the investigator at Occasion 1;

3. Not able to stop maintenance therapy.
The following medicactions should be stopped before and during the study:

a. topical or systemic anti-inflammatory therapy with anti-IgE (>6 months);

b. corticosteroids inhaled or nasal sprays (>6 weeks);

c. oral corticosteroids >8 weeks;

d. LTRAs >4 weeks;

e. cromones >2 wk;

f. anticholinergics >1 wk;

g. long-acting oral antihistamines >7 days;

h. short-acting oral antihistamines > 2 days;

i. theophylline >3 days.

j. No other nasal sprays (other than ICS) cromoglycate >2 wk;

k. nasal antihistamines >2 days;

l. xylomethazolin and NaCl 0.9% >1 day;

4. Use of topical corticosteroid containing cr¨¨mes on maintenance basis on the site of investigation (volar side of underarms, or elbows);

5. History of serious food or medication allergy or anaphylaxis;

6. History of alcohol or drug abuse;

7. Desensibilization therapy in the past;

8. Vaccinations in the past 1 month;

9. Viral respiratory tract infections within 3 weeks;

10. Nasal polyps;

11. Nasal surgery in the past 3 months;

12. Not able to collaborate in the study;

13. Treatment with any investigational drug for at least 3 months prior to this study or ¡Ý3 clinical trial participations in the last year;

14. Positive serology to hepatitis B or C or human immunodeficiency virus (HIV);

15. Blood donation of more than 500 ml during the previous 3 months (men) or 4 months (women), according to Sanquin guidelines.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	26-04-2005
Aantal proefpersonen:	20
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	13-09-2005

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	NL372
NTR-old	NTR412
Ander register	: P04.230
ISRCTN	ISRCTN34415480

Resultaten

Samenvatting resultaten
N/A