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

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| **Submission date**<br>27/01/2006 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>27/01/2006 | **Overall study status**<br>Completed | |
| **Last Edited**<br>25/08/2009 | **Condition category**<br>Respiratory | |

**Plain English summary of protocol**
Not provided at time of registration

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
NTR412; P04.230

# Study information

## Scientific Title

## Study objectives
Added 25/08/09:
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.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Received from local medical ethics committee

## Study design
Randomised double blind placebo controlled parallel group trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Not specified

## Study type(s)
Other

## Participant information sheet

## Health condition(s) or problem(s) studied
Atopic rhinitis

## Interventions
Subjects underwent a nasal allergen challenge with a relevant allergen.

## Intervention Type
Other

## Phase
Not Specified

## Primary outcome measure

Primary study objectives:
1. To test the reproducibility, in atopic subjects with a clinically stable allergic rhinitis of:
1.1. SPT
1.2. 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:
2.1. Exhaled nasal air
2.2. Peripheral blood
2.3. Nasal lavage
2.4. Nasal brush

### Secondary outcome measures
To identify an appropriate study population for intervention studies with anti-allergic agents such as anti-IL13.

### Overall study start date
26/04/2005

### Completion date
26/08/2005

## Eligibility

### Key inclusion criteria
1. Male or female subjects
2. 18-50 years of age with atopic rhinitis

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Upper age limit
50 Years

### Sex
Both

### Target number of participants
20

### Key exclusion criteria
1. Current smokers (<6 months stopped) or ex-smokers (>10 pack years)
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 medications should be stopped before and during the study:
3.1. topical or systemic anti-inflammatory therapy with anti-IgE (>6 months)
3.2. corticosteroids inhaled or nasal sprays (>6 weeks)
3.3. oral corticosteroids >8 weeks
3.4. LTRAs >4 weeks; cromones >2 weeks; anticholinergics >1 week
3.5. long-acting oral antihistamines >7 days
3.6. short-acting oral antihistamines > 2 days; theophylline >3 days
3.7. No other nasal sprays (other than ICS) cromoglycate >2 weeks
3.8. nasal antihistamines >2 days
3.9. xylomethazolin and NaCl 0.9% >1 day
4. Use of topical corticosteroid containing creams 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. Desensibilisation 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 >3 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

### Date of first enrolment
26/04/2005

### Date of final enrolment
26/08/2005

## Locations

### Countries of recruitment
Netherlands

### Study participating centre
**Zernikedreef 10**
Leiden
Netherlands
2333 CL

## Sponsor information

### Organisation
Centocor Inc. (USA)

### Sponsor details
200 Great Valley Parkway
Pennsylvania
Malvern
United States of America
19355-1307

### Sponsor type
Industry

### ROR
https://ror.org/05af73403

## Funder(s)

### Funder type
Industry

### Funder Name
Centocor Inc. (USA)

## Results and Publications

### Publication and dissemination plan
Not provided at time of registration

### Intention to publish date

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary
Not provided at time of registration

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/04/2007 | | Yes | No |