

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

<b>Submission date</b> 27/01/2006	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 27/01/2006	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 25/08/2009	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data

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

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
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

**Study type(s)**

Other

**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(s)**

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

**Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Upper age limit**

50 years

**Sex**

All

**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)

**ROR**

<https://ror.org/05af73403>

## **Funder(s)**

**Funder type**

Industry

**Funder Name**

Centocor Inc. (USA)

# Results and Publications

## 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?
<a href="#">Results article</a>	results	01/04/2007		Yes	No