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

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

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
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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?
Results article	results	01/04/2007		Yes	No