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

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

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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