Phenotypes of Adults with Non-Atopic Asthma.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON29228

Source
NTR

Brief title
PANAMA

Health condition

Non-atopic asthma
Adults

Niet-atopisch astma
Volwassenen

Sponsors and support

Primary sponsor: Medical Centre Leeuwarden, Department of respiratory medicine
Source(s) of monetary or material Support: Stichting Longgeneeskunde Fryslan

Intervention

Outcome measures

Primary outcome

Study 1: Characterizing patients with non-atopic asthma with respect to clinical, functional

and inflammatory parameters. Separate subtypes of non-atopic asthma will be defined by unbiased cluster analysis.

Study 2: The association between level of NO in exhaled air, percentage of eosinophils in induced sputum and extent of sinus disease as assessed by CT sinus score will be investigated by correlation analyses.

Study 3: Sensitivity, specificity, positive and negative predictive value of the eNose in detecting sinus disease in non-atopic asthma.

Secondary outcome

N/A

Study description

Background summary

Non-atopic asthma is a poorly understood heterogeneous condition and it is often more severe, less responsive to therapy and more likely to result in fixed airflow limitation. Several clinical subtypes have been described but it is unknown whether these are associated with distinct types of airway inflammation, responses to therapy or disease outcome.

This project is a cross sectional survey in patients with non-atopic asthma.

The objective of this study is to define different phenotypes and to detect risk factors of severity.

Study objective

Characterization of subjects with non-atopic asthma and phenotyping of the disease by linking clinical, functional and molecular markers will:

1. Give more insight in the underlying pathophysiological mechanisms of non-atopic asthma;

2. Show that different subtypes of non-atopic asthma can be identified by specific functional or non-invasive inflammatory markers;

3. Reveal distinct risk factors of severity and poor quality of life.

Study design

All data will be collected in two visits, which will be less than 2 weeks apart.

Intervention

N/A

Contacts

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Eligibility criteria

Inclusion criteria

1. Outpatients with non-atopic asthma, determined by negative alatop;

2. Age 18 yrs or older;

3. Pulmonologist's diagnosis of asthma;

4. Documented reversibility in FEV1 of >= 12% predicted OR airway hyperresponsiveness to inhaled methacholine.

Exclusion criteria

1. Patients with smoking history of > 10 packyears and persistent airflow obstruction (post

bronchodilator FEV1 < 80%pred): excluded if reversibility in FEV1 < 12% predicted OR TLCO< 80%pred;

2. Pregnancy;

3. Other pulmonary diseases or non-related major co-morbidities.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Factorial
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2010
Enrollment:	200
Type:	Anticipated

Ethics review

Positive opinion

Date:	15-02-2010
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 33169

Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL2100
NTR-old	NTR2217
CCMO	NL29219.099.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON33169

Study results

Summary results
N/A