Phenotypes of Adults with Non-atopic Asthma; Mechanisms and Aetiology

Published: 05-10-2009
Last updated: 19-03-2025

Study 1: The objective of this study is to thoroughly characterize a large group of patients with non-atopic asthma clinically, functionally and with respect to inflammatory parameters and define 3-4 major phenotypes of this disease using unbiased...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Observational invasive

Summary

ID

NL-OMON33169

Source
ToetsingOnline

Brief title
PANAMA

Condition

- Bronchial disorders (excl neoplasms)

Synonym
asthma, bronchitis

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Leeuwarden
Source(s) of monetary or material Support: Stichting Longgeneeskunde Fryslan

Intervention

Keyword: asthma, non-allergic, non-atopic, phenotyping

Outcome measures

Primary outcome

Study 1: the 3-4 separate subtypes of non-atopic asthma as 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

not applicable

Study description

Background summary

Non-atopic or intrinsic asthma is a heterogeneous condition that is less well understood than the classic allergic asthma that usually starts in childhood. Non-atopic asthma is often more severe, less responsive to therapy and more likely to result in fixed airflow limitation. Several clinical subtypes of non-atopic asthma have been described, but it is unknown whether these are associated with distinct types of airway inflammation, responses to therapy or disease outcome.
Sinus disease is supposed to be an important factor complicating asthma control, especially in non-atopic patients. However, the relationship between inflammation in upper and lower airways in non-atopic asthma is unclear. In addition, it is unknown whether non-invasive measurements of exhaled breath might predict the extend of inflammation in upper and lower airways in patients with non-atopic asthma.
Meticulous characterization of subjects with non-atopic asthma and phenotyping

of the disease by linking clinical, functional and molecular markers seems to be critical for further understanding of the underlying pathophysiological mechanisms. This will hopefully lead to phenotype-specific therapies that might improve the outcome in this group of patients.

Study objective

Study 1: The objective of this study is to thoroughly characterize a large group of patients with non-atopic asthma clinically, functionally and with respect to inflammatory parameters and define 3-4 major phenotypes of this disease using unbiased cluster analysis.

Study 2: In this second part we will investigate whether levels of nitric oxide (NO) in exhaled air are related to inflammatory processes in upper or lower airways in non-atopic asthma.

Study 3: In the third part we will determine the diagnostic accuracy of the electronic nose (eNose) in establishing the sensitivity, specificity, positive and negative predictive value for detecting sinus disease in non-atopic asthma

Study design

Study 1: This will constitute the baseline project of a prospective longitudinal follow up study of a large cohort (n=200) of patients with non-atopic asthma. Inclusion period: Oct 2009-Jan 2012.

Study 2: a cross-sectional analysis will be performed to determine the relationship between levels of exhaled NO, the type of lower airway inflammation and the extent of nasal sinus disease in 200 patients with non-atopic asthma.

Study 3: the potential of the electric nose to discriminate non-atopic asthma patients with and without sinus disease will be prospectively investigated by cross-sectional comparison between groups. In this part we will use results obtained in a study where the eNose was trained to develop an algorithm to discriminate patients with confirmed sinus disease from controls (AMC).

Study burden and risks

The burden associated with these studies includes *.. 2 hospital visits, during which different measurements will be done. An interview, physical examination, routine blood tests and lung function tests will be performed. Also an exhaled nitric oxide measurement and exhaled volatile organic compounds analysis (electronic nose) will be done.
All patients will perform sputum induction (for cell counts and pathogen

detection) which has shown to be well tolerated even by severe asthmatics in previous studies.
All patients will be submitted to CT-scanning of the nasal sinuses and nasal endoscopy by an ENT-specialist. The risk of and discomfort caused by these procedures is small.

The results of these studies may be important for the group of non-atopic asthmatic patients, as it will identify different subtypes of patients and unravel the underlying mechanisms. This will hopefully give the clinician support to diagnose different types of non-atopic asthma and lead to phenotype-specific therapies that might improve outcome in this group of patients. Hereby it might also help to reduce the personal and socioeconomic burden of the disease.

Contacts

Public
Medisch Centrum Leeuwarden

Postbus 888
8901BR Leeuwarden
NL
Scientific
Medisch Centrum Leeuwarden

Postbus 888
8901BR Leeuwarden
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

non-atopic asthma
age >= 18 yr

Exclusion criteria

allergy
COPD without features of asthma
pregnancy

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-01-2010
Enrollment:	200
Type:	Actual

Ethics review

Approved WMO

Date:	05-10-2009
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 29228
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL29219.099.09
OMON	NL-OMON29228