Adult onset asthma: the first 5 years

Published: 06-02-2009 Last updated: 06-05-2024

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Ethical review	-
Status	Pending
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Observational invasive

Summary

ID

NL-OMON33765

Source ToetsingOnline

Brief title Adult onset asthma: the first 5 years

Condition

• Bronchial disorders (excl neoplasms)

Synonym adult onset asthma, asthma

Research involving Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum **Source(s) of monetary or material Support:** Astma Fonds

Intervention

Keyword: adult onset, Asthma, phenotypes

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Outcome measures

Primary outcome

This is a descriptive study, without real outcome parameters. By performing

clusteranalysis, several phenotypes of late onset asthma will be defined.

Secondary outcome

n.a.

Study description

Background summary

Adult-onset asthma is a poorly understood, heterogeneous condition. It differs from childhood-onset asthma in that it is often more severe, less responsive to therapy and more likely to result in fixed airflow limitation. Several clinical subtypes of adult onset asthma have been described, but it is unknown whether these are associated with distinct types of airway inflammation, responses to therapy or disease outcome. Studies suggest that eosinophilic inflammation that persists despite corticosteroid treatment is a risk factor of severe disease and accelerated decline in lung function, especially in the first years of the disease.

Study objective

This project is the cross-sectional part of a large-scale longitudinal follow-up survey in patients with adult-onset asthma. The objective of this part of the survey is to define different phenotypes of adult onset asthma and to detect risk factors of severity.

Specific Aims:

 To define different subtypes of adult-onset asthma, and investigate whether these subtypes differ with respect to disease severity or quality of life
To investigate cross-sectionally whether recent onset asthma differs from later stages of adult-onset asthma, with respect to clinical, functional and inflammatory parameters

3. To investigate whether specific subtypes of adult-onset asthma can be identified by functional or non-invasive inflammatory markers

Study design

- Study 1 will represent the baseline part of a longitudinal follow up study of a cohort of 200 patients with adult-onset asthma. In this study, the patients will be thoroughly characterized by clinical, functional and inflammatory markers.

- In study 2, we will cross-sectionally analyse the differences between patients with recent-onset asthma (1-5 years) and longstanding adult-onset asthma (> 5 years).

- In study 3, the role of functional and *breatheomics* in the diagnosis of distinct subtypes of adult-onset asthma will be analysed by cross-sectional comparison between groups

Study burden and risks

Study 1 and 2: The burden associated with these studies includes a hospital visit, during which an intake interview, a physical examination, routine blood tests ,lung function, exhaled nitric oxide measurement, exhaled volatile organic compounds analysis (electronic nose) will be done. All subjects will also perform sputum induction (for differential cell counts and pathogen detection) which in our own experience as well as based on literature is well tolerated even by severe asthmatics.

Study 3: Seventy five subjects (who also participated in the previous studies) will be submitted to nasal endoscopy and sinus CT-scanning for quantitative scoring of mucosal swelling. The risk of and discomfort caused by these procedures is small.

The results of the study may be important for the group of asthmatic patients as it will identify different subtypes of patients with adult-onset asthma and unravel the underlying mechanisms, which will hopefully lead to phenotype-specific therapies that might improve outcome in this neglected group of patients. Thus might also help to reduce the personal and socioeconomic burden of the disease.

Contacts

Public Academisch Medisch Centrum

Meibergdreef 9 1105 AZ NL Scientific Academisch Medisch Centrum

Meibergdreef 9 1105 AZ NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

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

Inclusion criteria

- 18 75 years
- Patients with adult-onset asthma (i.e. asthma that started after the age of 18)
- Pulmonologist's diagnosis of asthma (from mild persistent to severe persistent)

- Documented reversibility in FEV1 of >9% predicted or airway hyperresponsiveness to inhaled methacholine.

Exclusion criteria

- patients with smoking history > 10 packyears, fixed airflow obstruction (postbronchodilator FEV1 < 80%) and reversibility in FEV1 < 9% predicted.

- pregnancy

- other pulmonary diseases or non-related major co-morbidities

Study design

Design

Study type: Observational invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Basic science	

Recruitment

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Recruitment status:	Pending
Start date (anticipated):	01-01-2009
Enrollment:	200
Туре:	Anticipated

Ethics review

Not available

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register CCMO **ID** NL25979.018.08