Adult Onset asthma and Inflammatory Sub-phenotypes

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Phenotyping of patients who are in an early state of adult-onset asthma (< 1 year the physician diagnosis of asthma and > 18 year of age) by linking clinical, functional and non-invasive inflammatory markers will:*Reveal distinct risk factors...

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

Summary

ID

NL-OMON33012

Source
ToetsingOnline

Brief title
Adonis

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: Ministerie van OC&W,GlaxoSmithKline,Unrestricted grant GlaxoSmithKline

Intervention

Keyword: adult onset, Asthma, phenotypes

Outcome measures

Primary outcome

This is a descriptive study, without real outcome parameters. By performing cluster analysis, several phenotypes of recent late onset asthma will be defined.

Potential risk factors are assessed at baseline (phase 1) and related to the change in lungfunction over time and exacerbation rate. Linear regression will be used to analyse the association between potential predicting factors and decline in FEV1 (ml.yr) and exacerbation rate during the follow-up. Logistic regression will be used to estimate RR/OR with 95% CI*s for accelerated decline in FEV1 and exacerbation rate.

Secondary outcome

n.v.t.

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

Phenotyping of patients who are in an early state of adult-onset asthma (< 1 year the physician diagnosis of asthma and > 18 year of age) by linking clinical, functional and non-invasive inflammatory markers will:
*Reveal distinct risk factors of severity and poor quality of life.
*Provide evidence that recent onset asthma in adulthood might be linked to airway infection or linked to environmental factors.

Describe this cohort of patients during 2 years:
*To define risk factors of accelerated decline in lungfunction and exacerbations frequency.

Study design

* Phase 1 will represent the baseline part of a longitudinal follow up study of a cohort of 200 patients who are in an early stage of adult onset asthma. In this study, the patients will be thoroughly characterized by clinical, functional and inflammatory markers.

* Phase 2, prospective follow-up during 2 years.

Study burden and risks

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

Phase 2: During the follow-up the patient will visit the hospital every 6 months. During every visit an interview, physical examination, routine blood test and short lungfunction test will be done.

The results of the study may be improtant for the group of asthmatic patients as it will identify different subtypes of patients with recent adult-onset asthma and unravel the underlying mechanisms, which will hopefully lead to phenotype-spefific 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

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- 18 to 75 years
- Adult-onset asthma (i.e. asthma that started after the age of 18)
- Physicians diagnosis of asthma < 1 year prior enrolment
- Documented reversibility in FEV1 of > 12 % predicted and 200 ml or airway hyperresponsiveness to inhaled methacholine (PC20 < 8 mg/ml)

Exclusion criteria

- Patients with smoking history > 10 packyears, fixed airflow obstruction (post bronchodilator FEV1 < 80%) and reversibility in FEV1 < 12% predicted.
- Pregnancy

- Other pulmonary diseases or non-related major-comobidities.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2009
Enrollment:	200
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	ID
CCMO	NL27379.018.09