

Adult Onset Asthma: the first 5 years.

No registrations found.

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

Summary

ID

NL-OMON22527

Source

Nationaal Trial Register

Brief title

TAKE5

Health condition

Adult onset asthma

Severe asthma

Phenotyping

Markers

Sponsors and support

Primary sponsor: Amsterdam Medical Centre, department of pulmonology

Source(s) of monetary or material Support: Netherlands Asthma Foundation 3208027

Intervention

Outcome measures

Primary outcome

Studie 1: Characterizing patients with adult onset asthma with respect to clinical, functional and inflammatory parameters. Subtypes will be defined by cluster analysis; risk factors of disease and poor quality of life will be defined.

Studie 2: Clinical, functional and inflammatory parameters will be compared between 100 patients with recent onset asthma (1-5yr) and 100 patients with longstanding adult onset asthma (>5yr).

Studie 3: Three well defined subtypes will be compared by measurements of small airway function and sputum cells.

Secondary outcome

N/A

Study description

Background summary

Adult onset asthma is a poorly understood heterogeneous condition. It differs from childhood asthma that 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. Studies suggest that eosinophilic inflammation that persist despite corticosteroid treatment is a risk factor of severe disease and accelerated decline in lung function, especially in the first year of the disease.

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 and to detect risk factors of severity.

Study objective

Phenotyping of patients with adult onset asthma by linking clinical, functional and molecular markers will:

1. Reveal distinct risk factors of severity and poor quality of life;
2. Provide evidence that recent onset asthma in adulthood is relatively more severe;
3. Show that different subtypes of adult onset asthma can be identified by specific functional or non-invasive inflammatory markers.

Study design

All data will be collected during 1 visit.

Intervention

N/A

Contacts

Public

M. Amelink
Academic Medical Center
Dept. Pulmonology, F5-260
Meibergdreef 9

Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5661660

Scientific

M. Amelink
Academic Medical Center
Dept. Pulmonology, F5-260
Meibergdreef 9

Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5661660

Eligibility criteria

Inclusion criteria

1. Age between 18-75 years;
2. Physicians diagnosis of asthma after age of 18;
3. Physicians diagnosis of asthma >1 year prior enrolment;
4. Documented reversibility in FEV1>12% and 200 ml or Airway hyperresponsiveness to inhaled methacholine (PC20<8mg/ml) or Diurnal variation in PEF of >20% (with twice daily reading >10%).

Exclusion criteria

1. Smoking history >10py and a fixed airflow obstruction (FEV1 <80%pb and FEV1/FVC<0.70pb) without reversibility in FEV1>12% and 200ml;
2. Pregnancy;
3. Physician's diagnosis of asthma in childhood;
4. Other pulmonary diseases or non related major co-morbidities;
5. Diffusion capacity (TLCO/VA) <80%;
6. Episodes of dyspneu or multiple use of inhalde pulmonary medication in childhood (5-12yr).

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:	Pending
Start date (anticipated):	22-06-2009
Enrollment:	200
Type:	Anticipated

Ethics review

Positive opinion	
Date:	04-06-2009

Application type:

First submission

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
NTR-new	NL1728
NTR-old	NTR1838
Other	MEC AMC : 08/358
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results

N/A