Astma ontstaan op volwassen leeftijd: de eerste twee jaar.

No registrations found.

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

Summary

ID

NL-OMON28266

Source
NTR

Brief title
ADONIS

Health condition

adult onset asthma
phenotyping
markers

Sponsors and support

Primary sponsor: Academic Medical centre
Source(s) of monetary or material Support: Investigator Initiated Study Unrestricted Grant by GlaxoSmithKline

Intervention

Outcome measures

Primary outcome

Phase 1: Cross-sectional assessment.

3-4 separate subtypes will be defined by cluster analysis; risk factors of severe disease and poor quality of life will be defined.

Phase 2: Follow-up during 4 years.

The cohort of patients will be prospectively followed for 4 years. The course of the disease during treatment by their own physician/ pulmonologist will be observed. Potential risk factors will be assessed at baseline (patients' clinical characteristics, different non-invasive markers of airway inflammation, lungfunction, airway hyperresponsiveness) and related to the change in lung function and exacerbation rate over time.

Secondary outcome

N/A

Study description

Background summary

Rationale:
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.

Objective:

Phase 1 (cross-sectional part): to define different phenotypes of recent adult-onset asthma and describe risk factors of severity of asthma and poor quality of life.

Phase 2 (follow-up part): to determine the predictive effect of clinical characteristics and inflammatory markers (analysed in the cross-sectional part) on subsequent change in post-bronchodilator FEV1 and frequency of exacerbations and hospitalisations.

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 4 years.

Study objective

The aims of the present study are:

1. To give a comprehensive description of 200 adults (> 18 yr) with recently diagnosed adult-onset asthma (< 1 yr);

2. To define clinical, lung function or inflammatory or mixed phenotypes of adult onset asthma and risk factors to develop the disease;

3. To define risk factors of accelerated decline in lungfunction in adult onset asthma;

4. To define risk factors of frequent exacerbations and hospitalisations in adult onset asthma.

Study design

1. Phase 1: cross-sectional assessment;

2. Phase 2: follow-up after 6, 12, 18 and 24 months.

25-09-2012: Instead of a 2-year follow-up, this will take 4 years.

Intervention

Not applicable, observational study.

Contacts

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Eligibility criteria

Inclusion criteria

1. 18 to 75 years;

2. Adult-onset asthma (i.e. asthma that started after the age of 18);

3. Physicians diagnosis of asthma < 1 year prior enrolment;

4. Documented reversibility in FEV1 of > 12 % predicted and 200 ml or airway hyperresponsiveness to inhaled methacholine (PC20 < 8 mg/ml);

5. Diural variation in PEF of ¡Ý 20% (with twice daily reading, more than 10%);

6. Documented history of prompt deterioration (FEV1) with > 25% reduction in oral or inhaled corticosteroid dose (within 4 weeks).

Exclusion criteria

1. Patients with smoking history > 10 packyears, who have fixed airflow obstruction (post bronchodilator FEV1 < 80% and FEV1/FVC < 0.70) and without reversibility in FEV1 > 12 % predicted and 200 ml;

2. Pregnancy;

3. Physician's diagnosis of asthma in childhood;

4. Other pulmonary diseases or non-related major-comorbidities;

5. Episodes of severe dypneu in childhood (age 5-12 yr);

6. Diffusion capacity < 80% (TLCO/VA).

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):	09-06-2009
Enrollment:	200
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	08-06-2009
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	NL1736
NTR-old	NTR1846
Other	MEC AMC : 09/101
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A