Astma ontstaan op volwassen leeftijd: de eerste twee jaar.

Gepubliceerd: 08-06-2009 Laatst bijgewerkt: 18-08-2022

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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON28266

Bron
NTR

Verkorte titel
ADONIS

Aandoening

adult onset asthma
phenotyping
markers

Ondersteuning

Primaire sponsor: Academic Medical centre
Overige ondersteuning: Investigator Initiated Study
Unrestricted Grant by GlaxoSmithKline

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

Not applicable, observational study.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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).

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Factorieel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	09-06-2009
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	08-06-2009
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1736
NTR-old	NTR1846
Ander register	MEC AMC : 09/101
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A