

Adult Onset Asthma: the first 5 years.

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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...

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

Samenvatting

ID

NL-OMON22527

Bron

Nationaal Trial Register

Verkorte titel

TAKE5

Aandoening

Adult onset asthma
Severe asthma
Phenotyping
Markers

Ondersteuning

Primaire sponsor: Amsterdam Medical Centre, department of pulmonology

Overige ondersteuning: Netherlands Asthma Foundation 3208027

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

All data will be collected during 1 visit.

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

Publiek

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

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

Wetenschappelijk

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

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

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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%).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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).

Onderzoeksopzet

Opzet

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

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	22-06-2009
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum: 04-06-2009
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	NL1728
NTR-old	NTR1838
Ander register	MEC AMC : 08/358
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten

N/A