Diagnostic accuracy of minimally-invasive biomarkers for sputum eosinophilia in adult-onset asthma patients.

Gepubliceerd: 12-05-2014 Laatst bijgewerkt: 18-08-2022

1) FeNO, blood eosinophils and total IgE will have a moderate diagnostic accuracy to detect sputum eosinophilia in adult-onset asthma patients. 2) There will be differences in accuracy between sub-groups of patients.

Ethische beoordeling	Niet van toepassing
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON27218

Bron
NTR

Aandoening

adult-onset asthma
sputum eosinophilia

Ondersteuning

Primaire sponsor: Academic Medical Center, Amsterdam
Overige ondersteuning: Dutch Lung Foundation
foundation for pulmonary medicine Friesland,
Dutch Foundation for the Prevention of Asthma
Glaxo Smith Kline,

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Diagnostic accuracy of FeNO, IgE and blood eosinophils in detecting patients with sputum eosinophila ≥3%, as expressed by the:
a) AUC
b) sensitivity and corresponding threshold at a fixed specificity of 95%
c) specificity (95%CI) and corresponding threshold at a fixed sensitivity of 95%.

Toelichting onderzoek

Achtergrond van het onderzoek

Sputum eosinophilia ≥3% has shown to be a good predictor of responsiveness to corticosteroid treatment, but sputum induction and differential sputum cell counts are only feasible in specialized clinics, are not always successful and do not give immediate results. Less direct measures of airway inflammation such as fraction of exhaled nictric oxide (FeNO), blood eosinophils and IgE are more easily performed and widely available. Several studies have investigated the diagnostic accuracy of these markers in detecting sputum eosinophilia ≥3%, but always in a mixed population including both childhood- and adult-onset asthma. We will investigate the diagnostic accuracy of these markers for differentiating between patients with and without eosinophilia in adult-onset asthma.

We will perform a retrospective analysis of data derived from 336 asthmatic patients included in three completed prospective observational studies (acronyms: Adonis, Take-5, PANAMA). Patients were recruited from an academic and several non-academic pulmonary outpatient clinics in the Netherlands. The study protocols aimed to determine FeNO, blood eosinophils, IgE and sputum eosinophils in all these patients in 1-2 visits less than 2 weeks apart.

Doel van het onderzoek

1) FeNO, blood eosinophils and total IgE will have a moderate diagnostic accuracy to detect sputum eosinophilia in adult-onset asthma patients.

2) There will be differences in accuracy between sub-groups of patients.

Onderzoeksopzet

Cross-sectional

Onderzoeksproduct en/of interventie

NA

Contactpersonen

Publiek

Department of Respiratory Medicine, F5-260
Academic Medical Centre, University of Amsterdam
PO Box 22700, 1100 DE Amsterdam

G.A. Westerhof
Amsterdam
The Netherlands
+31 - 20 - 56 61660

Wetenschappelijk

Department of Respiratory Medicine, F5-260
Academic Medical Centre, University of Amsterdam
PO Box 22700, 1100 DE Amsterdam

G.A. Westerhof
Amsterdam
The Netherlands
+31 - 20 - 56 61660

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Age: 18-75 years

Physician’s diagnosis of asthma, combined with documented reversibility in FEV1 of > 12% of predicted value or a positive inhaled methacholine provocation test (PC20 < 8mg/ml) or diurnal variation in PEF of >20% (with twice daily reading >10%)

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Smoking history of >10 pack years combined with fixed airflow obstruction (FEV1 <80% of predicted and FEV1/FVC <0.70) without reversibility in FEV1 <12% or with a diffusion capacity <80% (TLCO/VA).

Other pulmonary diseases.

Non-related major co-morbidities.

Pregnancy.

Physician’s diagnosis of childhood asthma or other chronic respiratory diseases in childhood, frequent episodes of dyspnea as a child, or use of a bronchodilator or other asthma medication in childhood.

Patients without sputum eosinophils results (reference test).

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	13-05-2014
Aantal proefpersonen:	336
Type:	Werkelijke startdatum

Ethische beoordeling

Niet van toepassing

Soort: Niet van toepassing

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	NL4375
NTR-old	NTR4589
Ander register	NTR 1838 (08/358 MEC AMC), NTR 2217 (NL 29219.099.09 CCMO) : NTR 1846 (09/101 METC AMC)

Resultaten