# Diagnostic accuracy of minimallyinvasive biomarkers for sputum eosinophilia in adult-onset asthma patients.

No registrations found.

Ethical review	Not applicable	
Status	Recruitment stopped	
Health condition type	-	
Study type	Observational non invasive	

## Summary

#### ID

**NL-OMON27218** 

Source NTR

#### **Health condition**

adult-onset asthma sputum eosinophilia

### **Sponsors and support**

**Primary sponsor:** Academic Medical Center, Amsterdam **Source(s) of monetary or material Support:** Dutch Lung Foundation foundation for pulmonary medicine Friesland, Dutch Foundation for the Prevention of Asthma Glaxo Smith Kline,

### Intervention

#### **Outcome measures**

#### **Primary outcome**

1 - Diagnostic accuracy of minimally-invasive biomarkers for sputum eosinophilia in ... 7-05-2025

Diagnostic accuracy of FeNO, IgE and blood eosinophils in detecting patients with sputum eosinophila  $\geq$  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%.

#### Secondary outcome

-Evaluate the diagnostic accuracy of FeNO, IgE and blood eosinophils in patient subgroups (eg, gender, race, smoking status, oral corticosteroid treatment status, asthma severity, BMI, nasal polyps, atopy).

-Evaluate whether combinations of FeNO, IgE and blood eosinophils improved diagnostic accuracy, as determined by the AUC.

-Build a multivariable logistic regression model including patient characteristics and marker combinations for the optimal discrimination between patients with and without sputum eosinophilia.

## **Study description**

#### **Background summary**

Sputum eosinophilia  $\geq$ 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  $\geq$ 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.

#### **Study objective**

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.

#### Study design

**Cross-sectional** 

#### Intervention

NA

## Contacts

#### Public

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

G.A. Westerhof Amsterdam The Netherlands +31 - 20 - 56 61660 **Scientific** Department of Respiratory Medicine, F5-260 <br> Academic Medical Centre, University of Amsterdam <br> PO Box 22700, 1100 DE Amsterdam

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

## **Eligibility criteria**

### **Inclusion criteria**

Age: 18-75 years

3 - Diagnostic accuracy of minimally-invasive biomarkers for sputum eosinophilia in ... 7-05-2025

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%)

### **Exclusion criteria**

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).

## Study design

## Design

Study type:	Observational non invasive	
Intervention model:	Other	
Allocation:	Non controlled trial	
Masking:	Single blinded (masking used)	
Control:	N/A , unknown	

### Recruitment

. . .

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	13-05-2014
Enrollment:	336
Туре:	Actual

4 - Diagnostic accuracy of minimally-invasive biomarkers for sputum eosinophilia in ... 7-05-2025

## **Ethics review**

Not applicable Application type:

Not applicable

## **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
 NL4375

 NTR-old
 NTR4589

 Other
 NTR 1838 (08/358 MEC AMC), NTR 2217 (NL 29219.099.09 CCMO) : NTR 1846 (09/101 METC AMC)

## **Study results**