# The development of a clinical test to assess the inflammatory phenotype of asthma

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Goals1. To investigate whether analysis of antibodies directed against active Beta1 and Beta 2-integrins (CD29/CD18) and FcγRII (CD32) of primed eosinophils allows the diagnosis of eosinophilic asthma as compared to analysis of sputum...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Lower respiratory tract disorders (excl obstruction and infection)
Study type	Observational invasive

# Summary

### ID

NL-OMON38417

**Source** ToetsingOnline

Brief title AIR

### Condition

• Lower respiratory tract disorders (excl obstruction and infection)

#### Synonym

Asthma, bronchial hyperreactivity, inflammatory lung disease

#### **Research involving**

Human

### **Sponsors and support**

**Primary sponsor:** Universitair Medisch Centrum Utrecht **Source(s) of monetary or material Support:** Ministerie van OC&W

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### Intervention

Keyword: asthma, bloodtest, phenotype, sputumtest

#### **Outcome measures**

#### **Primary outcome**

To investigate whether analysis of antibodies directed against active  $\beta 1/\beta 2$ -

integrins (CD29/CD18) and FcyRII (CD32) of primed eosinophils allows the

diagnosis of eosinophilic asthma as compared to analysis of sputum

eosinophilia.

#### Secondary outcome

1. Measurement of antibodies against active  $\beta 1/\beta 2$ -integrins

and  $\mathsf{Fc}\gamma\mathsf{RII}$ 

- 2. Measuring specific protein profiles in serum of asthma patients by
- proteomics
- 3. FeNO measurement

# **Study description**

#### **Background summary**

Asthma is a heterogeneous disease and can be classified by level of control, disease severity and the inflammatory phenotype. However, these different domains overlap and classification of patients according to these characteristics has caused confusion in the literature. Concerning the inflammatory phenotype international consensus is present regarding the diagnostic power of induced sputum. This methodology is, however, difficult to implement in general practice. Local inflammation is associated with a complex combination of systemic pro- and anti-inflammatory signals that induce changes in responsive leukocytes. These changes can be used as read-out for type and degree of inflammatory disease.

Hypothesis: in asthma the analysis of type and degree of inflammation in

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peripheral blood by changes in phenotypes of leukocytes is at least as reliable as analysis of induced sputum. This will facilitate the diagnosis of inflammatory phenotypes in asthma, as general application of induced sputum is not feasible.

#### Study objective

#### Goals

1. To investigate whether analysis of antibodies directed against active Beta1 and Beta 2-integrins (CD29/CD18) and FcγRII (CD32) of primed eosinophils allows the diagnosis of eosinophilic asthma as compared to analysis of sputum eosinophilia.

2. To evaluate the applicability of antibodies against active  $\beta 1/\beta 2$ -integrins and FcyRII in symptomatic asthma patients as a test to diagnose eosinophilic and neutrophilic asthma.

3. To determine specific protein profiles in serum of asthma patients by proteomics for the development of a diagnostic test.

4. To evaluate the effectiveness of this new test in comparison with FeNO.

#### Study design

- Diagnostic study
- Cross-sectional cohort

#### Study burden and risks

The only SAE that could possibly occur is acute bronchoconstriction caused by the hypertonic saline administrated during sputum induction. This could lead acute hospitalisation if the patient does not respond well to the inhalation of bronchodilating medication. This is however a very rare complication and only one case report describing a fatal case has been published which was presumably caused by sputum induction. If the guideline of the European Task Force for sputum induction is followed, this risk is narrowed down to a marginal proportion.

# Contacts

#### Public

Universitair Medisch Centrum Utrecht

#### Heidelberglaan 100

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3584CX Utrecht NL **Scientific** Universitair Medisch Centrum Utrecht

Heidelberglaan 100 3584CX Utrecht NL

# **Trial sites**

### **Listed location countries**

Netherlands

# **Eligibility criteria**

#### Age

Adults (18-64 years) Elderly (65 years and older)

### **Inclusion criteria**

- Patients with adult asthma
- Age 18-75
- Visiting the outpatient clinic of the UMC and CMH Utrecht
- Suitable for sputum induction

## **Exclusion criteria**

• smoking at present or in the last 12 months and/or a past history of more than 10 pack years

- antibiotic treatment for a respiratory tract infection <4 weeks prior to the study
- proven allergic bronchopulmonary aspergillosis.

• Other (chronic) Inflammatory disease(s) such as rheumatoid arthritis and inflammatory bowel disease

# Study design

## Design

Study type: Observational invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Diagnostic	

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	08-05-2012
Enrollment:	115
Туре:	Actual

# **Ethics review**

Approved WMO	
Date:	26-09-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO	
Date:	06-06-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

# **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

ССМО

**ID** NL37707.041.11