

# Prevalence, incidence and adherence of “difficult-to-treat” adult asthma in the Netherlands.

Gepubliceerd: 30-07-2012 Laatste bijgewerkt: 18-08-2022

Aims: 1. To describe the prevalence and incidence of difficult-to-treat adult asthma in the Netherlands; 2. To describe factors associated with adherence with pulmonary medication in patients with difficult-to-treat airway disease; 3. To score...

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

## Samenvatting

### ID

NL-OMON26986

### Bron

Nationaal Trial Register

### Aandoening

prevalence  
adherence  
difficult-to-treat  
asthma  
inhalation technique  
inhaled corticosteroids

Prevalentie  
therapietrouw  
astma  
inhalatietechniek  
corticosteroiden

### Ondersteuning

**Primaire sponsor:** Academic Medical Centre,  
Amsterdam

**Overige ondersteuning:** Unrestricted grant by Novartis

## Onderzoeksproduct en/of interventie

### Uitkomstmaten

#### Primaire uitkomstmaten

1. The prevalence and incidence of patients with difficult-to-treat asthma in the Netherlands;<br>
2. Factors associated with adherence to pulmonary medication in difficult-to-treat asthma;<br>
3. Primary: Inhalation technique scores in adherent patients with difficult-to-treat asthma;<br>
4. Primary: The proportion of patients with truly severe asthma (i.e. uncontrolled asthma or oral corticosteroid dependent asthma despite good adherence with high dose ICS and adequate inhalation technique).

## Toelichting onderzoek

### Achtergrond van het onderzoek

Rationale:

Patients with severe refractory asthma pose a major healthcare problem. It has become increasingly clear that, for the development of new targeted therapies, there is an urgent need for further characterisation and classification of these patients. However, the exact prevalence of patients with severe refractory asthma is unknown and in addition to this, the question remains if patients who have difficult-to-treat asthma have truly severe refractory asthma or are not adherent with their medication or have an incorrect inhalation technique. Data on this is lacking.

Objective:

1. To describe the prevalence and incidence of “difficult-to-treat” adult asthma in the Netherlands.
2. To describe factors associated with adherence with pulmonary medication in patients with difficult-to-treat airway disease.
3. To describe the inhalation technique in adherent patients with difficult-to-treat airway

disease.

4. To compare patients' characteristics of patients with difficult-to-treat asthma with optimal treatment adherence and adequate inhalation technique and severe controlled asthma with optimal treatment adherence and adequate inhalation technique.

Study design:

Descriptive observational study.

### **Doel van het onderzoek**

Aims:

1. To describe the prevalence and incidence of difficult-to-treat adult asthma in the Netherlands;
2. To describe factors associated with adherence with pulmonary medication in patients with difficult-to-treat airway disease;
3. To score the inhalation technique in patients using high dose inhaled corticosteroids who are adherent to treatment;
4. To assess the prevalence of patients with truly severe, refractory asthma and describe the characteristics of these patients.

### **Onderzoeksopzet**

N/A

### **Onderzoeksproduct en/of interventie**

All patients listed in 73 community pharmacies and using inhaled corticosteroids will be selected, their characteristics will be encoded and translated into a database. This database will be send to the AMC.

From this database the codes of patients using high dose of inhaled corticosteroids will be selected. The pharmacies will translate these codes to the original patient numbers and send the patients questionnaires. These can be returned directly to the AMC.

From this database containing information about high dose ICS prescription, medication adherence, asthma control and patients characteristics the patients will be divided into 3 categories:

1. Asthma;
2. Mixed asthma/COPD (patients with asthma and  $\geq 10$ py);
3. COPD.

Patients with COPD will be excluded from further analyses and the prevalence and incidence of difficult-to-treat asthma and the adherence to inhaled therapy will be determined.

Additionally, all patients from aim 2 who are adherent with asthma treatment will receive inhalation technique assessment and instructions.

These groups are determined by:

1. Difficult-to-treat asthma;
2. Optimal treatment adherence;
3. Controlled or uncontrolled asthma.

## 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. All patients using inhaled corticosteroids for at least 3 months at least one receipt repeated;
2. Patients from study 1 using fluticasone equivalent of  $\geq 1000 \mu\text{g}$  or  $\geq 500\mu\text{g}$  fluticasone equivalent per day + maintenance of 5mg prednisone per day for at least 30 days;
3. Patients from study 2, who have collected  $\geq 70\%$  of prescriptions in the past 12 months.

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

COPD.

## 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 gestart  
(Verwachte) startdatum: 01-04-2012  
Aantal proefpersonen: 1500  
Type: Verwachte startdatum

## Ethische beoordeling

Positief advies  
Datum: 30-07-2012  
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	NL3403
NTR-old	NTR3546
Ander register	METC AMC : 2011_255
ISRCTN	ISRCTN wordt niet meer aangevraagd.

# Resultaten

## Samenvatting resultaten

N/A