# ASTHMA CONTROL COST-UTILITY RANDOMIZED TRIAL EVALUATION.

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1. A treatment strategy aimed at well controlled asthma is more (cost-)effective as compared to a treatment strategy aimed at achieving partly controlled asthma; 2. A treatment strategy aimed at well controlled asthma is (cost-)effective when the...

| | |
|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON22219

**Bron**
NTR

**Verkorte titel**
Accurate

**Aandoening**

Asthma

### Ondersteuning

**Primaire sponsor:** -
**Overige ondersteuning:** - Netherlands Organisation for Health Research and Development (ZON-MW, sub-programme Effects & Costs 80-82310-98-8627)
- Netherlands Asthma Foundation (NAF 3.4.07.044)
- Aerocrine (medical technology company)

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

Pharmaco-economics:<br>
1. Net health benefit;<br>
2. Cost-effectiveness;<br>
3. Cost-utility.

# Toelichting onderzoek

### Achtergrond van het onderzoek

Rationale:
The central question is whether an attempt to achieve complete control of all features of asthma, with accompanying high dosis of medication should be made, and whether patients and society value the potential incremental benefit sufficiently to concur with such a treatment approach. Therefore the aim of the study is to assess patient preferences and cost-effectiveness of two treatment strategies aimed at achieving different levels of clinical control:

1. Partly controlled asthma;

2. Controlled asthma.

A third strategy adds a nitric oxide measurement:

3. Controlled asthma based on exhaled nitric oxide as an additional disease marker.

In the third treatment strategy an algorithm was designed that combines the results of an NO-measurement and the composite score measurements. The question is whether this leads to better asthma control in a general practice population and whether it is a cost-effective addition.

Methods:
720 Patients with mild to moderate persistent asthma from general practices with a nurse practitioner or physician assistant, age 18-50 yr, need for daily treatment with inhaled corticosteroids (more then 3 months usage of inhaled corticosteroids in the previous year), will be identified via primary care patient registries, including Leiden, Nijmegen and Amsterdam areas. The design is a cluster-randomised trial with 40 general practices in all three arms and 12 months follow-up. The patients will visit the general practice at baseline, 3, 6, 9 and 12 months. At each planned and unplanned visit to the general practice treatment will be adjusted with support of an ICT-based asthma monitoring system supervised by a central coordinating specialist nurse. Patient preferences and utilities will be assessed by questionnaire and interview. Data on asthma control, treatment step, adherence to treatment, utilities and costs will be obtained every 3 months. Differences in societal costs (medication, other (health) care and productivity) will be compared to differences in the number of limited activity days and in quality adjusted life years (Dutch EQ5D, SF6D, e-TTO,

VAS).

**Doel van het onderzoek**

1. A treatment strategy aimed at well controlled asthma is more (cost-)effective as compared to a treatment strategy aimed at achieving partly controlled asthma;

2. A treatment strategy aimed at well controlled asthma is (cost-)effective when the treatment step is additionally guided by measurements of exhaled nitric oxide (NO) as compared to a treatment strategy aimed at achieving well controlled asthma or partly controlled asthma.

**Onderzoeksopzet**

Baseline, 3months, 6 months, 9months, 12 months + unplanned visits.

**Onderzoeksproduct en/of interventie**

1. PC-strategy: aiming to achieve partly controlled asthma based on asthma control measures;

2. C-strategy: aiming to achieve controlled asthma based on asthma control measures;

3. FeNO-strategy: aiming to achieve controlled asthma based on asthma control measures and an indirect marker of airways inflammation.

# Contactpersonen

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# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age 18-50 yr;

2. Doctors diagnosis of asthma;

3. A prescription of inhaled corticosteroid treatment in the last year;

4. Willing to change treatment step in order to follow the protocol;

5. Written informed consent.

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

1. Daily or alternate day oral corticosteroid therapy within 1 month before entering the study;

2. Inability to understand written or oral Dutch instructions;

3. Active diseases likely to interfere with the purpose of the study.

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | Gerandomiseerd |
| Blindering: | Open / niet geblindeerd |
| Controle: | Geneesmiddel |

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving gestart |
| (Verwachte) startdatum: | 01-07-2009 |
| Aantal proefpersonen: | 720 |
| Type: | Verwachte startdatum |

## Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

**Wordt de data na het onderzoek gedeeld:** Nog niet bepaald

# Ethische beoordeling

Positief advies

| | |
|---|---|
| Datum: | 09-04-2009 |
| 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 | NL1658 |
| NTR-old | NTR1756 |
| Ander register | METC LUMC : P08.237 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd |

# Resultaten

**Samenvatting resultaten**
N/A