# Towards better asthma control in children:is there a role for the asthma control test and exhaled nitric oxide?

Published: 16-07-2009
Last updated: 06-05-2024

Research questions:1. Is web-based monthly monitoring using the Asthma Control Test (ACT) cost-effective?2. Is asthma management guided by the fraction of nitric oxide in exhaled air (FENO) cost-effective?We hypothesize that both strategies are...

| | |
|---|---|
| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Bronchial disorders (excl neoplasms) |
| **Study type** | Interventional |

## Summary

### ID

NL-OMON37105

**Source**
ToetsingOnline

**Brief title**
Better Asthma Treatment: Monitoring with ACT and Nitric oxide.

### Condition

- Bronchial disorders (excl neoplasms)

**Synonym**
asthma

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam
**Source(s) of monetary or material Support:** Nederlands Astma Fonds;co-financiering wordt gezocht

## Intervention

**Keyword:** asthma control, children, exhaled nitric oxide, monitoring

## Outcome measures

### Primary outcome

Primary endpoint is the proportion of symptom free days during the last 4 weeks of the study. Power of the study is such that, with 87 children per group, an increase of the percentage of symptom free days of 18% (corresponding to 2.5 extra symptom free days per 2 weeks) as compared to the control group can be detected (power 80%, alpha=0.025). Taking into account some drop outs, we will include 100 patients per group.

Primary endpoint of the pilot study is the post-dexamethasone cortisol levels.

### Secondary outcome

Secondary endpoints are: costs, patient utilities, asthma related quality of life, symptoms, use of rescue and controller medication, bronchial hyperresponsiveness, FENO, lung function, exacerbations, ICS dose.

Differences in societal costs will be compared to differences in the number of limited activity days (CEA) and in quality adjusted life years (CUA).

Secondary endpoints of the pilot study: basal salivary cortisol levels.

# Study description

### Background summary

Background: Asthma affects approximately 150.000 children in the Netherlands. Despite the availability of effective treatment, 30-50% of children with asthma are poorly controlled. This project will compare the effect on paediatric asthma control of two innovative monitoring strategies in comparison to usual

care.
The pilot study will test if the overnight low-dose dexamethasone suppression test is predictive for corticosteroid hypersensitivity and resistance.

## Study objective

Research questions:
1. Is web-based monthly monitoring using the Asthma Control Test (ACT) cost-effective?
2. Is asthma management guided by the fraction of nitric oxide in exhaled air (FENO) cost-effective?
We hypothesize that both strategies are superior to usual care, with more symptom free days (as primary endpoint) during the last 4 weeks of the study.
Research questions pilot study: (1) does the 0,25 mg DST correlate with ICS dose in asthmatic children? (2) do children, resistant in the 0,25 mg DST (>90 percentile) need a higher corticosteroid dose for asthma treatment compared to children with non-resistant 0,25 mg DST (<90 percentile)? (3) do children, hypersensitive in the 0,25mg DST (<10 percentile) need a lower corticosteroid dose for asthma treatment compared to children with non-hypersensitive 0,25mg DST (>=10 percentile)? (4) Can the 0,25mg DST predict systemic adverse effect of pituitary adrenal axis suppression with an accuracy of >80%?

## Study design

In this multi-centre study 3 monitoring strategies will be compared. Patients will be randomly assigned to 3 groups:
- control group: treatment according to national guidelines
- Web group: an Internet program with monthly ACTs guides treatment
- FENO group: FENO guides treatment
During 12 months there are 5 clinic visits. Every visit an ACT will be taken and FENO measured. During run-in (4 weeks), 2 weeks before every clinic visit and 4 weeks before the final visit patients will record symptoms and medication use in a diary. At the start and end of the study lung function will be tested, a bronchial provocation test will be performed and the Pediatric Asthma Quality of Life Questionnaire (PAQLQ) and Strengths and Difficulties questionnaire (SDQ) will be taken. The Cost Questionnaire (costQ) en EuroQol-5 dimensions (EQ-5D) will be assessed at every clinic visit. Treatment steps will be taken according to Dutch guidelines on pediatric asthma.
In the pilot study the 0.25 mg DST will be performed at home. Two salivary samples for measurement of cortisol are obtained on 2 sequential days after an overnight fast at 8 a.m. On the first day, a capsule containing 0.25 mg (modified by body surface area) dexamethasone is ingested at 8 p.m. In the second sample dexamethasone level is measured. The saliva samples will be sent to the hospital by mail. The post-dexamethasone cortisol level will be used as a measure of corticosteroid sensitivity. Outcome parameters are post-dexamethasone cortisol levels, ICS dose and basal salivary cortisol

levels.

**Intervention**

In this study proposal 2 interventions will be compared to usual care.
(1) Web group: an Internet program with monthly ACTs guides treatment
- if ACT < 20: step up in treatment
- if ACT >= 20: step down or no change (decided by treating physician)
(2) FENO group: FENO guides treatment
- if ACT < 20 and FENO >= 25 ppb: step up
- if ACT < 20 and FENO < 25 ppb: no change
- if ACT >= 20 and FENO < 25 ppb: step down
- if ACT >= 20 and FENO >= 25 ppb en < 50 ppb: no change
- if ACT >= 20 and FENO >= 50 ppb: step up
Treatment steps accoridng to guidelines of the Dutch Paediatric Respiratory Group. .

**Study burden and risks**

In this study children will visit the clinic for 1-3 extra visits in 1 year.
During the study extra inevstigations are:
- ACT at every visit, takes 1-2 minutes
- measuring FENO, 5 minutes, noninvasive test
- questionnaires: Paediatric Asthma Quality of Life Questionnaire (20 min), twice during th study; Strengths and Difficulties Questionnaire (SDQ) (10 min) twice; Cost questionnaire (CostQ) (5 min), at every visit (5x), EQ-5D (10 min), at every visit (5 x).
- follow-up: ACT, takes 1-2 minutes, evaluation form, takes 4-5 minutes
- in he webgroup: ACT to be filled in every 4 weeks (2 min)
- spirometry: FEV1 measurement twice during the study (15 min), noninvasive test. In general children enjoy this test.
- Bronchoprovocation tests, twice during the study, 20-80 min. During this test children may become dyspnoic. For safety reasons this test will not be performed if FEV1/FVC is below 70%. After the test children will receive an inhaled bronchodilator to reverse bronchoconstriction.
The pilot study will add the following investigations: 0,25 mg DST(2x), questionnaire: fill-in form for saliva sampling (2x).

# Contacts

**Public**
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr Molewaterplein 60

3015 GJ
NL
**Scientific**
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr Molewaterplein 60
3015 GJ
NL

# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

## Inclusion criteria

Childern 4-18 years old with atopic asthma, using inhaled corticosteroids for at least 3 months preceding the study. Children and/ or their parents should have access to the Internet at home. Children should be able to perform FENO measurements.

## Exclusion criteria

Exclusion criteria are active smoking, chronic lung disease other than asthma, recent (<1 year) or multiple ICU admissions, use of a LTRA with a low dose inhaled corticosteroid (< Budesonide 2 dd 400 ug or eq), and inability of parents or older children (>11 years) to read or understand Dutch.

# Study design

## Design

| | |
|---|---|
| Study type: | Interventional |
| Intervention model: | Parallel |
| Allocation: | Randomized controlled trial |
| Masking: | Open (masking not used) |
| Control: | Active |
| Primary purpose: | Diagnostic |

## Recruitment

NL

| | |
|---|---|
| Recruitment status: | Recruitment stopped |
| Start date (anticipated): | 02-02-2010 |
| Enrollment: | 300 |
| Type: | Actual |

# Ethics review

| | |
|---|---|
| Approved WMO Date: | 16-07-2009 |
| Application type: | First submission |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 02-02-2010 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 08-02-2010 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 20-07-2011 |
| Application type: | Amendment |

| | |
|---|---|
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |
| Approved WMO Date: | 22-12-2011 |
| Application type: | Amendment |
| Review commission: | METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam) |

# 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 |
|---|---|
| CCMO | NL26964.078.09 |