Better Asthma Treatment: Monitoring with ACT and Nitric oxide.

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26506

Source
Nationaal Trial Register

Brief title
BATMAN study

Health condition

Asthma control, monitoring, children, exhaled nitric oxide

Sponsors and support

Primary sponsor: Erasmus Medical Center, Sophia Children’s Hospital, Department of Pediatric Pulmonology
Source(s) of monetary or material Support: Astmafonds
ZonMW
Fonds NutsOhra

Intervention

Outcome measures

Primary outcome

Primary endpoint is the proportion of symptom free days (SFD) during the 4 weeks before the final visit (t =12 months).

Secondary outcome

Secondary endpoints are:

1. Daily and nocturnal symptoms, limitation of activities, use of rescue and controller medication as assessed with diary cards during the 4 weeks before visit t = 12 months;

2. Asthma related quality of life assessed with the PAQLQ;

3. Compliance with treatment during the 4 weeks before visit t=12 months, as assessed by diary cards and pharmacy data;

4. Airway hyperresponsiveness (PD20 methacholine);

5. FENO;

6. Spirometry (FEV1, FEF25%);

7. Exacerbations: unscheduled doctor visits related to asthma, systemic steroid courses, emergency room visits and hospital admissions all related to asthma;

8. ICS dose;

9. Patient utilities (EQ-5D);

10. Costs (CostQ).

Study description

Background summary

Rationale: 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.

Objectives: This study aims to answer two research questions:

1. Does web-based monthly monitoring using the Asthma Control Test (ACT) improve asthma control? Is this strategy cost-effective?

2. Does asthma management guided by the fraction of nitric oxide in exhaled air (FENO)

improve asthma control? Is this strategy cost-effective?

We hypothesize that both strategies are superior to usual care, with more symptom free days (SFD) during the last 4 weeks of the study.

Study design: This is a prospective, controlled, multi-centre study, in which 300 children will be randomly allocated to 1 of 3 treatment algorithms.

Study population: 300 children, 4 -18 yrs, with allergic asthma and using ICS will be enrolled. Children and/ or their parents should have access to Internet at home. Exclusion criteria are active smoking, pulmonary conditions other than asthma and inability to perform FENO measurements.

Intervention: children will be randomly allocated to 1 of 3 treatment algorithms:

1. Control group: treatment according to national guidelines;

2. FENO group: FENO guides treatment;

3. Web group: an Internet program with monthly ACTs guides treatment.

Main study parameters/endpoints: Primary endpoint is the proportion of SFD during the last 4 weeks of the study. Secondary endpoints are: asthma related quality of life, patient utilities, costs, symptoms, use of rescue and controller medication, bronchial hyperresponsiveness, FENO, lung function, exacerbations, ICS dose.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Participation in this trial does not carry any risks and the burden to the patients is minimal. This study follows usual care as much as possible with a minimum of extra clinic visits (1-3 in 12 months). At every visit patients fill in the ACT, CostQ and EQ-5D (all short questionnaires). At the start and end of the study, in addition, lung function tests and bronchoprovocation tests will be performed and the paediatric asthma quality of life questionnaire (PAQLQ, 23 items) and strengths and difficulties questionnaire (SDQ) will be filled in. These 2 visits will last around 2.5 hours.
Patients and their parents will be asked to fill in diary cards during run-in, 2 weeks before visit t = 4 months and t=8 months and 4 weeks before the final visit. Diary cards address questions on symptoms, exercise tolerance and use of medication. Completing diary cards

will cost 1-2 minutes every day.
Children in the web-arm fill in an ACT every 4 weeks (duration 2-3 minutes).

This study is performed in children as asthma is a highly prevalent disorder in children, and asthma in children differs form asthma in adults in several ways, including differing phenotypes, and assessment and monitoring of asthma control.

Study objective

This study aims to answer two research questions:

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2. Does asthma management guided by the fraction of nitric oxide in exhaled air (FENO) improve asthma control? Is this strategy cost-effective?

We hypothesize that both strategies are superior to usual care, with more symptom free days (SFD) during the last 4 weeks of the study.

Study design

t= -1, t= 0, 4, 8 and 12 months.

Intervention

Children will be randomly allocated to 1 of 3 treatment algorithms:

1. Control group: treatment according to national guidelines;

2. FENO group: FENO guides treatment;

3. Web group: an Internet program with monthly ACTs guides treatment.

Contacts

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Eligibility criteria

Inclusion criteria

1. Children 4-18 years old with allergic asthma, using inhaled corticosteroids for at least 3 months preceding the study;

2. Children and/or their parents should have access to the Internet at home;

3. Children should bij able to perform FENO measurements.

Exclusion criteria

1. Active smoking;

2. Chronic lung disease other than asthma;

3. Inabilily 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:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2009
Enrollment:	300
Type:	Actual

Ethics review

Positive opinion

Date:	08-09-2009
Application type:	First submission

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	NL1881
NTR-old	NTR1995
Other	METC Erasmus MC/Nationaal Astma Fonds projectummer/ZonMw projectnummer : MEC-2009-164/3408039/171002101
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A