Better Asthma Treatment: Monitoring with ACT and Nitric oxide.

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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…

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON26506

Bron
Nationaal Trial Register

Verkorte titel
BATMAN study

Aandoening

Asthma control, monitoring, children, exhaled nitric oxide

Ondersteuning

Primaire sponsor: Erasmus Medical Center, Sophia Children’s Hospital, Department of Pediatric Pulmonology
Overige ondersteuning: Astmafonds
ZonMW
Fonds NutsOhra

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Active smoking;

2. Chronic lung disease other than asthma;

3. Inabilily of parents or older children (>11 years) to read or understand Dutch.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-12-2009
Aantal proefpersonen:	300
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	08-09-2009

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

Resultaten

Samenvatting resultaten
N/A