e-Monitoring of Asthma Therapy to Improve Compliance in children.

Gepubliceerd: 02-11-2010 Laatst bijgewerkt: 18-08-2022

Adherence to inhaled corticosteroids in children with asthma will improve by sending tailored sms-reminders to the parents.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29009

Bron
Nationaal Trial Register

Verkorte titel
e-MATIC

Aandoening

asthma, adherence, inhaled corticosteroids, real time medication monitoring (RTMM), sms-reminder

Ondersteuning

Primaire sponsor: Erasmus MC te Rotterdam
Evalan BV (manufacturer of RTMM equipment)
GlaxoSmythKline (pharmaceutical company)
Overige ondersteuning: ZONMW

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Percentage of inhalations taken within a 6 hour timeframe around the expected time of inhalation.

Toelichting onderzoek

Achtergrond van het onderzoek

Background:

Asthma still is the most common chronic childhood disease in industrialised countries. Asthma control in children is poor, partly due to poor medication adherence. Effective interventions are needed to improve medication adherence.

Aim:

The aim of the project is to use a Real-Time Medication Monitoring system (RTMM) to improve adherence to inhalation corticosteroids in children with asthma and to study the impact of improved adherence on effectiveness and cost-effectiveness of treatment.

Design:

A multicenter, randomized controlled trial.

Patients:

Included are children (younger than 12 years) with moderate to severe asthma, who have been using inhaled corticosteroids (ICS) as a pressurized metered dose inhaler (pMDI) for asthma for at least 3 months.

Intervention:

All children receive an RTMM-device, but only in the intervention group SMS-messages are sent to the parents and in case the child has a mobile phone - to the child to warn that a dose is at risk of omission. The sms-reminding is tailored in that warnings are only sent if non-adherence is likely to occur.

Outcome measures:

In both groups RTMM data are used to determine adherence, which is the primary outcome measure of this study. This outcome is defined as the percentage of prescribed dosages taken by the child within a 6 our time-frame around the expected time of inhalation (from 3 ours before until 3 hours after). Secondary outcome measures are asthma control, exacerbations and disease-specific quality of life collected through the PAQLQ questionnaire, interviews and medical health records. Online focus groups and patient questionnaires will be used to collect data on parental and children's acceptance of the system. An economic evaluation will be performed adopting a societal perspective, including all relevant healthcare costs and productivity loss of the parents. Furthermore, a decision-analytic model will be developed that includes different levels or forms of adherence and the outcomes, both clinical and costs, attributed to each level or form of adherence as well as different price levels for RTMM.

Doel van het onderzoek

Adherence to inhaled corticosteroids in children with asthma will improve by sending tailored sms-reminders to the parents.

Onderzoeksopzet

The study period per patient is one year.

Onderzoeksproduct en/of interventie

All children will receive a real time medication monitoring (RTMM) device that is connected to the pressurized metered dose inhaler (pMDI) with inhaled corticosteroids (ICS). Immediately after each inhalation, a signal is sent to the research database. This information is compared to the expected time of inhalation and thus adherence is determined. Only in the intervention group, sms-reminders are sent to parents of children that are at risk of forgetting to take their ICS.

Contactpersonen

Publiek

Erasmus MC
Afdeling apotheek
Cluster 7
Postbus 2040
E.C. Vasbinder
Rotterdam 3000 CA

The Netherlands
+31 (0)10 7033202

Wetenschappelijk

Erasmus MC
Afdeling apotheek
Cluster 7
Postbus 2040
E.C. Vasbinder
Rotterdam 3000 CA
The Netherlands
+31 (0)10 7033202

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Children younger than 12 years old;

2. Diagnosed with asthma for at least 6 months;

3. ICS use for at least 3 months using a pMDI;

4. At least one parent or care giver has a mobile phone.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Refusal to participate in the study.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel

Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2011
Aantal proefpersonen:	220
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL2467
NTR-old	NTR2583
Ander register	ABR : 34219
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A