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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29009

Source
Nationaal Trial Register

Brief title
e-MATIC

Health condition

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

Sponsors and support

Primary sponsor: Erasmus MC te Rotterdam
Evalan BV (manufacturer of RTMM equipment)
GlaxoSmythKline (pharmaceutical company)
Source(s) of monetary or material Support: ZONMW

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

1. Asthma controll;

2. Asthma exacerbations;

3. Disease specific quality of life;

4. Acceptance of e-monitoring bij parents and children.

Moreover, an economic evaluation will be performed adopting a societal perspective, including all relevant healthcare costs and productivity loss of the parents.

Study description

Background summary

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.

Study objective

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

Study design

The study period per patient is one year.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

Refusal to participate in the study.

Study design

Design

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2011
Enrollment:	220
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

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	NL2467
NTR-old	NTR2583

Register	ID
Other	ABR : 34219
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A