Compliance Objectively measured in a Multicultural Population of children Living In Amsterdam Needing inhaled Corticosteroids for Effective asthma treatment.

No registrations found.

Ethical review	Not applicable
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON29533

Source
NTR

Brief title
COMPLIANCE

Health condition

compliance, inhaled corticosteroids, ethnicity, children, therapietrouw, inhalatiecorticosteroiden, etniciteit, kinderen

Sponsors and support

Primary sponsor: drs Vasbinder EC, dr Wolf B, drs Dahhan N, dr Bemt PMLA van den Sint Lucas Andreas Ziekenhuis, Jan Tooropstraat 164, 1061 AE, Amsterdam, 0205108590, e.vasbinder@slaz.nl
Source(s) of monetary or material Support: -Astmafonds (onder voorbehoud)
-Agis zorgverzekeringen

Intervention

Outcome measures

Primary outcome

The proportion of noncompliant administrations of the total number of administrations.

Secondary outcome

- The MARS questionnaire data, compared to the RTMEMS as a gold standard.

- The association of determinants with non-compliance.

Study description

Background summary

The majority of children with asthma in Amsterdam have a non-Dutch background. Data on noncompliance in this group are controversial. Primary aim of this study is to determine objectively measured noncompliance to inhaled corticosteroids (ICS) in a multicultural population of children with asthma in Amsterdam. Objectively means that the data are measured using a reliable, electronic measurement tool, which has never been used before in studies on compliance of inhalation therapy in The Netherlands.
A secondary aim is to compare electronic data on noncompliance with the results of a questionnaire into self reported noncompliance by parent and child. The study is designed as a cross sectional study of 9 months duration, in which the compliance of ICS is measured in a cohort of 150 non-native (75 Turkish, 75 Moroccan) and 75 native Dutch children with asthma (per patient noncompliance is monitored during 3 months). Objective measurements of compliance will be performed using a pressurized Metered-Dose Inhaler (pMDI) connected to a Real Time remote Medication Event Monitoring System (RTMEMS). The Medication Adherence Report Scale (MARS) questionnaire will be used to investigate self reported compliance. Determinants to be registered include age, gender, ethnicity, language skills, parental level of education, family income, hospitalisation rates, frequency of visits to the paediatric ambulatory clinic, housing and smoking habits of parents. Medication beliefs of parents will be measured using the Beliefs about Medicines Questionnaire (BMQ).
Electronically measured noncompliance is the primary outcome measure; the influence of the determinants on noncompliance will be analysed. As a secondary outcome measure the accuracy of the information on noncompliance from the MARS questionnaire will be compared to the RTMEMS.

The child’s paediatrician will be informed on the study results of his patients, in order to use these data for compliance enhancement. These study results reflect the exact day-to-day use

of the ICS by the child.

Study objective

The primary aim of this study is to investigate objectively, electronically measured noncompliance to inhaled corticosteroids in a multicultural population of children with asthma. Furthermore, the association of determinants such as ethnicity, age, gender, parental level of education, family income and insurance status with non-compliance will be determined.

A secondary aim will be the comparison of objectively, electronically measured noncompliance (provided by the RTMEMS technology) to self reported noncompliance as determined with the MARS (Medication Adherence Report Scale) questionnaire.

Study design

The study period per patient is 3 months.

Intervention

None (observational study approach)

Contacts

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Eligibility criteria

Inclusion criteria

1. Patient is attending the pediatric outpatient department of the St Lucas Andreas Hospital in Amsterdam, AMC or BovenIJ.

2. ICS use during at least the preceding 6 months using a pMDI.

3. Age of max. 11 years old.

4. Dutch, Turkish or Moroccan ethnicity

Exclusion criteria

1. Refusal to participate

2. Incapability of understanding the RTMEMS instructions. (this exclusion criterium only counts for the electronic measurements)

Study design

Design

Study type:	Interventional
Intervention model:	Other

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-01-2009
Enrollment:	225
Type:	Actual

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	NL671
NTR-old	NTR1373
Other	ABR formulier : 22626
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A