COmpliance Objectively measured in a Multicultural Population of children Living In Amsterdam Needing inhaled Corticosteroids for Effective asthmatreatment. (COMPLIANCE)

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Primary aim is to study electronically measured compliance to inhaled corticosteroids (ICS) in a multicultural population of children with asthma in Amsterdam. A secondary aim will be to compare electronical data on compliance with parent reports.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Upper respiratory tract disorders (excl infections)
Study type	Observational non invasive

Summary

ID

NL-OMON32079

Source
ToetsingOnline

Brief title
COMPLIANCE

Condition

- Upper respiratory tract disorders (excl infections)
- Lifestyle issues

Synonym
asthma, bronchopulmonary hyperreactivity

Research involving
Human

Sponsors and support

Primary sponsor: Sint Lucas Andreas Ziekenhuis
Source(s) of monetary or material Support: AGIS (zorgverzekeraar)

Intervention

Keyword: children, compliance, ethnicity, inhaled corticosteroids

Outcome measures

Primary outcome

Electronically measured compliance is the primary outcome measure; the

influence of the determinants on compliance will be analysed.

Secondary outcome

As a secondary outcome measure the accuracy of the information on compliance

from the questionnaire will be compared to the RTMEMS.

Study description

Background summary

Non-compliance is a major issue in asthma treatment. Ethnic minorities have an increased risk of poor asthma control. The majority of children with astma in Amsterdam have a non-Dutch background. However, data on compliance in this group are controvertial.

Study objective

Primary aim is to study electronically measured compliance to inhaled corticosteroids (ICS) in a multicultural population of children with asthma in Amsterdam. A secondary aim will be to compare electronical data on compliance with parent reports.

Study design

The study is designed as a cross sectional study in which the compliance of ICS is measured in a cohort of 75 Turkish, 75 Moroccan and 75 Dutch children with asthma 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). Questionnaires 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 pediatric ambulatory clinic, medication beliefs of parents, housing and smoking habits of parents.

Study burden and risks

In this study patients are asked to participate in 2 interviews and to use a pressurized Metered-Dose inhalator connected to RMEMS, that is supplied by the investigators and which contains their usual inhaled corticosteroid for 3 months. There isn't any therapeutic intervention in this observational study. Apart from an initial telephone call, patients visit the hospital twice in a three month period. The interviews mentioned above, take place during these visits. For the majority of the participating patients this approximates their regular frequency of visiting the pediatric outpatient clinic.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

- Patient attending the pediatric outpatient department of the St. Lucas Andreas hospital or the Academic Medical Centre.
- Patient has been treated with fluticason for at least 3 months using a pressurized metered-dose inhaler.
- Maximum age: 11 years old.
- Dutch, Moroccan, Turkish ethnicity.

Exclusion criteria

- Patient refuses to participate in the study.
- Patient is not capable of using the equipment for electronic measurement of compliance correctly#.;#These patient are requested to participate in the interview. In addition, patient characteristics are collected to investigate whether these patients differ from the ones that are capable of using the RTMEMS-equipment.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

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

Ethics review

Approved WMO Date:	06-10-2008
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
Other	3567 (Nederlands Trial Register)
CCMO	NL22626.029.08