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

Gepubliceerd: 11-07-2008 Laatst bijgewerkt: 18-08-2022

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Ethische beoordeling	Niet van toepassing
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON29533

Bron
NTR

Verkorte titel
COMPLIANCE

Aandoening

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

Ondersteuning

Primaire 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
Overige ondersteuning: -Astmafonds (onder voorbehoud)
-Agis zorgverzekeringen

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

The study period per patient is 3 months.

Onderzoeksproduct en/of interventie

None (observational study approach)

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Refusal to participate

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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-01-2009
Aantal proefpersonen:	225
Type:	Werkelijke 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	NL671
NTR-old	NTR1373
Ander register	ABR formulier : 22626
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten

N/A