Diagnostic value diurnal peak flow and FEV1 variation assessed electronically with home spirometry in childhood asthma.

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To determine whether variation of PEF and FEV1 in children, using an electronic home spirometer, adds to the confirmation or rejection of the diagnosis asthma in children when suspected.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Interventional

Summary

ID

NL-OMON30702

Source
ToetsingOnline

Brief title
Electronical Peak flow and Lung function Monitoring 6 (EPLM 6)

Condition

- Bronchial disorders (excl neoplasms)

Synonym
asthma

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken

Source(s) of monetary or material Support: Astra Zeneca,Astra-Zeneca Nederland

Intervention

Keyword: Childhood Asthma, Diagnostics, Home spirometry, Peak Expiratory Flow

Outcome measures

Primary outcome

Daily variation of PEF and FEV1 between the asthma and non asthma group and

within the asthma group before and after the start of inhaled corticosteroids.

Secondary outcome

The cut-off point with the highest likelyhood ratio (sensitivity/1-specificity)

for the golden standard of asthma diagnosis

(pediatrician/pediatric-pulmonologist diagnosed asthma) wil be determined by

performing receiver operating ratio (ROC)-analyses. This analysis is primarily

'pilot' based. The estimated power will be to low for definit conclusions.

Study description

Background summary

The diagnosis asthma in school-aged children is primarily based on history and physical examination. In a clinical practice lung function measurements are commonly used to support the diagnosis. The downside of lung function tests is that they only provide a snapshot impression of the lung function, rather than reflect the variability of lung function in a variable disease as asthma. This variability of lung function can be measured using portable peak flow (PEF)-meters. In the past, this was done using mechanical PEF-meters and hand-written diaries. Due to large overlap between healthy and asthmatic children, PEF variation is not commonly used anymore as a diagnostic tool in asthma. Research has shown, however, that mechanical PEF-meters and hand-written diaries are unreliable. Previous work from our group showed that healthy children using electronic PEF meters (recording value, time and date on a micro-chip) had significantly lower reference values for PEF variability than previously described, while well treated children with mild to moderate

persistent asthma showed quite high variability in lung function. From these data, the hypothesis emerged that electronic home spirometers can be helpful in diagnosing asthma in children.

Study objective

To determine whether variation of PEF and FEV1 in children, using an electronic home spirometer, adds to the confirmation or rejection of the diagnosis asthma in children when suspected.

Study design

This study will investigate the diagnostic value of PEF and FEV1 variation (diagnostic test) in childhood asthma. The gold standard for the diagnosis asthma will be: asthma diagnosed by a pediatrician or pediatric pulmonologist based on international guidelines (GINA), using results from history, physical examination and lung function tests (flow-volume curves before and after broncho-dilators, fractional exhaled nitric oxide and methacholine challenge), as is usual practice in the Isala Klinieken. The pediatrician or pediatric pulmonologist will be blinded for the results of the home spirometry. After the diagnosis asthma is confirmed (or rejected), the influence of inhaled corticosteroids (when appropriate) on home spirometry will be assessed.

Intervention

During the first phase none. When asthma is diagnosed, inhaled corticosteroids will be prescribed.

Study burden and risks

A slight worsening of symptoms may occur during the wash-out phase in some children. However, due to the strict inclusion and exclusion criteria, this is very unlikely to occur.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

- schoolchildren reffered to the pediatric out-patient clinic for diagnostics of exclusion of asthma
- age 6-16 years
- capable of performing reproducible lung function measurements at home
- proper understanding of the dutch language
- informed consent

Exclusion criteria

- other chronic or acute disease capable of influencing the study results
- refferal of children with an established diagnosis of asthma, who remain symptomatic despite treatement with inhaled corticosteroids.
- respiratory tract infection or use of systemic corticosteroids 4 weeks prior to the start of the study
- participation in another study
- use of systemic corticosteroids or long-acting β2 sympathicomimetics.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	06-03-2007
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	01-02-2007
Application type:	First submission
Review commission:	METC Isala Klinieken (Zwolle)

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
CCMO	NL14801.075.06