Electronically measured peak expiratory flow and FEV1 during respiratory symptoms in asthmatic children

Published: 01-02-2007
Last updated: 10-05-2024

To see if there is a clinically relevant and statisticallly significant decrease in lung function when children with mild to moderate persistent asthma feel the need to take bronchodilators.

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

Summary

ID

NL-OMON30426

Source
ToetsingOnline

Brief title
Electronical Peak flow and Lung function Monitoring 5 (EPLM 5)

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, Home spirometry, Peak Expiratory Flow, Respiratory symptoms

Outcome measures

Primary outcome

FEV1 and PEF when children have respiratory symptoms and take bronchodilators.

Secondary outcome

n/a

Study description

Background summary

Inhaled corticosteroids (ICS) are the cornerstone in asthma treatement, in adults as well as in children. When acute dyspneu occors, direct symptom relief is obtained by using B2 agonists. It is known that children with asthma and their parents have often difficulty in recognising symptoms of dyspneu and it is unknown wether the use of B2 agonists at home is due to an objective decrease in lung function.

A simple and non-invasive way to assess variation of airways obstruction is the use of home spirometry and peak flow (PEF) measurements. In contrast to mechanical PEF-meters and written diaries, children show high adherence to using electronic home spirometers. Results obtained by home spirometry show good agreement with lung function measured in hospitals and are therefore suitable to get an impression of the dergee and the variation of lung function at times of subjective need for bronchodilators. With this study the nature of the acute symptoms in pediatric asthma can be properly described.

Study objective

To see if there is a clinically relevant and statisticallly significant decrease in lung function when children with mild to moderate persistent asthma feel the need to take bronchodilators.

Study design

At the beginning and at the end of the study bronchial obstruction and reversibility of lung function will be assessed and exhaled NO will be

measured. A validated disease-specific quality of life questionnaire will also be filled in. During the study, children will record a symptomscore (VAS-scale) twice daily and, when feeling the need to take bronchodilators, just before taking them. At these times, they also will measure PEF and FEV1 on a portable spirometer. Once every 2 weeks these values will be downloaded on a PC.

Study burden and risks

n/a

Contacts

Public
Isala Klinieken

dokter van Heesweg 2
8000 GK Zwolle
Nederland
Scientific
Isala Klinieken

dokter van Heesweg 2
8000 GK Zwolle
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- schoolchildren with dokters' diagnosed asthma, monitored by a pediatrician.
- age 6-16 year
- familiar with the outpatient asthma clinic in Zwolle
- 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
- airway tract infection or use of systemic corticosteroïds 4 weeks prior to the start of the study
- participation in another trial
- use of systemic corticosteroids and long-acting β2 sympathicomimetics.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-02-2007
Enrollment:	50
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	NL14896.075.06