Improving clinical assessment of asthma by studying the relation between spirometry and the prediction of EIB

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23114

Source
Nationaal Trial Register

Health condition

Asthma, Children, Video

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: Medisch Spectrum Twente

Intervention

Outcome measures

Primary outcome

To study the reliability of assessment of airway obstruction by specialists by assessment/prediction of EIB based on videos before and after exercise, and based on pre-exercise pulmonary function

To compare the relation between prediction of EIB by specialists, pulmonary function results and pre- and post-exercise videos;

Secondary outcome

(C)-ACT

VAS dyspnoea score

Study description

Background summary

Diagnosis and monitoring of asthma in the clinical practice depends on adequate perception of symptoms by children and parents, anamnesis and physical examination. Those measurements are not specific nor sensitive in diagnosing asthma. Also elective pulmonary function testing is not informative. EIB can be identified with an exercise challenge test (ECT), however these tests are time-consuming and expensive. There is a need for objective tools to diagnose EIB in asthmatic children.
Evaluation of asthma symptoms in a home setting could lead to better insight in presence of symptoms, severity and control of asthma symptoms in children. Video evaluation of asthma symptoms could be a potential low-end and objective addition to the clinical practice of asthma, which could lead to improvement of the diagnostic process and monitoring of asthma in order to optimalize treatment, reduce cost and increase efficiency.

In order to use videos in a home setting, it has to be investigated if and how well specialists can assess dyspnoea on video material. By making video recordings of children before and after ECTs, the relationship between assesment of dyspnoea by specialist based on videos and pulmonary function can be explored in an experimental setting.
This study was designed to investigate whether paediatricians can predict the severity of EIB as measured with an ECT from the medical history, physical examination and pre-exercise video, and if the addition of pre-exercise lungfunction can improve this prediction.

The second aim of this study is to investigate the relation between asthma dyspnoea scores, as assessed by pediatricians from videos, and the severity of airway obstruction as measured with pulmonary function.

Study objective

We hypothesize that prediction of dyspnoea from videos are not related to asthma scores of physicians. We also hypothesize results of spirometry will not improve prediction and management of asthma.

Study design

Primary outcomes:

To study the reliability of assessment of airway obstruction by specialists;

To compare the relation between prediction of EIB by specialists, pulmonary function results and pre- and post-exercise videos;

We consider comparison between the prediction of specialists, video-analysis and pulmonary function tests as an objective addition to the clinical practice of asthma.

Secondary outcomes:

To study the relation between asthma symptoms, spirometry and the VAS dyspnea score filled in by the subjects (children) and their parents before and after the ECT.

We encounter patient- and parent-recorded findings as a valuable secondary study-endpoint, because how a patient or parent perceive the severity of asthma and the level of control, is of great importance for the ability to self-manage the asthma.

Measurements:

- Pulmonary function testing pre- and post-exercise

- Exercise challenge tests

- Pre- and post-exercise videos

- Classification of EIB (no, mild, moderate and severe EIB)

- Dyspnoea features

- Likert scale

Intervention

None, only observations

Contacts

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Eligibility criteria

Inclusion criteria

-Clinical history of asthma or suspected of having asthma;

-Age between 4-17 years;

-Ability to perform reproducible lung function tests, i.e. coefficient of the predicted value variation in 3 of 5 consecutive measurements < 5%.

Exclusion criteria

-Airflow limitiation in baseline spirometry (forced expiratory volume in the first second (FEV1), <60% of predicted);

- Spirometry induced bronchoconstriction;

- Use of short- or longacting bronchodilators <24 hours before testing.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Crossover
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-05-2015
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion Date:	08-12-2015
Application type:	First submission

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	NL5409
NTR-old	NTR5534
Other	: K15-05

Study results

Summary results
None