Using electronic nose measurements to capture subgroups of children with asthma.

No registrations found.

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

Summary

ID

NL-OMON25508

Source
Nationaal Trial Register

Health condition

asthma control in children

Sponsors and support

Primary sponsor: Academic Medical Centre
University of Amsterdam
Source(s) of monetary or material Support: investigator initiated study

Intervention

Outcome measures

Primary outcome

1. Asthma control score;

2. VOC’s of breath prints in exhaled air by gas chromatography mass spectrometry (GC-MS) and electronic nose (eNose).

Secondary outcome

1. Fractional exhaled Nitric Oxide;

2. FEV1, PEF.

Study description

Background summary

Recent clinical guidelines indicate that asthma management should focus on achieving a good level of asthma control. There seems to be subgroups of patients with remarkable inconsistencies between reported symptoms and the presence of airway inflammation. Therefore, phenotypic evaluation of these patients including reported symptoms and objective parameters of airway inflammation should be considered as the strategy of asthma management. The aim of our study is to explore the possibility of using exhaled breath to discriminate between groups of children with different levels of asthma control.

In this cross-sectional study data will be collected once per patient. Asthma control will be evaluated by questionnaire (in the asthmatic patients). Afterwards exhaled breath, FeNO and spirometry measurements will be performed. Spirometry will be measured at last by hand-held spirometer.

Study objective

The analysis of exhaled breath by electronic nose measurements can discriminate between subgroups of children with different levels of asthma control.

Study design

This is a cross-sectional study, only one timepoint.

Intervention

This will be a cross-sectional study. Data will be collected once per patient in a period of 6 months, in the same occasion as their routine visit in the outpatient clinics. Asthma control will be evaluated by (C)ACT questionnaire (in the asthmatic patients). Afterwards exhaled breath, fractional exhaled Nitric Oxide (FeNO) and spirometry measurements will be performed. Spirometry will be measured at last by hand-held spirometer.

Contacts

Public
Dept. Pulmonology, F5-259
Academic Medical Center
University of Amsterdam
P.O. Box 22700

Peter J. Sterk
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5668137 or +31 (0)20 5664356
Scientific
Dept. Pulmonology, F5-259
Academic Medical Center
University of Amsterdam
P.O. Box 22700

Peter J. Sterk
Amsterdam 1100 DD
The Netherlands
+31 (0)20 5668137 or +31 (0)20 5664356

Eligibility criteria

Inclusion criteria

1. Males and females aged 6 to 17 years (inclusive);

2. Parent/ guardian must be able to give written informed consent prior to participation in the study, which includes ability to comply with the requirements and restrictions listed in the consent form. Informed consent must be obtained prior to undertaking any study procedures;

3. Assent should be obtained from all children in the study where appropriate;

4. For children in the asthma groups, the diagnosis of asthma should be given by specialists according to the GINA guidelines;

5. For the control-group children should have no known respiratory or other systemic diseases.

Exclusion criteria

1. Known underlying respiratory tract disease like congenital airway abnormalities, cystic fibrosis, primary ciliary dyskinesia, bronchopulmonary dysplasia or bronchiectasis;

2. Known systemic or inflammatory diseases;

3. History or current evidence of an upper or lower respiratory infection or symptoms (including common cold) within 2 weeks of baseline assessment (assessment should be deferred);

4. The child has had a exacerbation (requiring ER attendance or hospital admission and /or a course of high dose OCS for at least 3 days duration) within 4 weeks of the baseline assessment (assessment should be deferred).

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	02-05-2012
Enrollment:	75
Type:	Anticipated

Ethics review

Positive opinion

Date:	25-04-2012
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	NL3257
NTR-old	NTR3410
Other	METC AMC : 2012_019
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A