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

Published: 12-04-2012
Last updated: 26-04-2024

The aims of our study are:1. To use electronic nose measurements to discriminate between well-defined groups of children with different levels of asthma control. 2. To use electronic nose measurements to distinguish between different levels of FeNO...

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

Summary

ID

NL-OMON37775

Source
ToetsingOnline

Brief title
Electronic nose measurements in children

Condition

- Bronchial disorders (excl neoplasms)

Synonym
asthma

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: asthma control, children, electronic nose

Outcome measures

Primary outcome

- asthma control score

- VOC*s of breath prints in exhaled air by gas chromatography mass spectrometry

(GC-MS) and electronic nose (eNose).

- Fractional exhaled Nitric Oxide

- FEV1, PEF

Secondary outcome

not applicable

Study description

Background summary

The electronic nose seems to be able to discriminate between different respiratory diseases. For asthma and COPD this discriminating capacity has already been demonstrated. In children, the possibility of electronic nose measurements has been less investigated. The electronic nose can be a usefull, objective and non-invasive diagnostic tool in the respiratory clinic.
There is a group of patients with inconsistencies between their rapported symptoms and the presence of airway inflammation. These patient are often difficult to treat.
With this study we want to explore the possibility of the electronic nose to discriminate between subgroups of children with different levels of asthma control.

Hypothesis:
We hypothesize that analysis of exhaled breath by electronic nose measurements can discriminate between subgroups of children with different levels of asthma control.

Study objective

The aims of our study are:
1. To use electronic nose measurements to discriminate between well-defined groups of children with different levels of asthma control.
2. To use electronic nose measurements to distinguish between different levels of FeNO as a possible marker of airway inflammation.
3. To evaluate whether electronic nose measurements can capture subgroups of children with asthma with a mismatch in between symptoms and inflammation.

Study design

This is 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 of the Academic Medical Centre and the VU University Medical Centre. The research will take a maximum of 30 minutes per patient.

For logistical reasons part of the data (asthma control score, lung function and FeNO and electronic nose values) to be used in this study will be extracted from a database of a concomitant study running in the department (UBIOPRED METC 2011_039)). These patients will be asked to give separate permission for the use of their anonymous data.

Asthma control will be evaluated by questionnaire. Afterwards exhaled breath, FeNO and spirometry measurements will be performed. Spirometry will be measured at last by hand-held spirometer (pikometer).

Study burden and risks

All procedures are non-invasive, safe and bring no discomfort to the participants.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

General inclusion criteria:
- Males and females aged 6 to 17 years
- 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.
- Assent should be obtained from all children in the study where appropriate.;For patients with asthma:
- Diagnosis of asthma given by specialists (data documented in patient records) according to the GINA guidelines.

Exclusion criteria

- Known underlying respiratory tract disease like congenital airway abnormalities, cystic fibrosis, primary ciliary dyskinesia, bronchopulmonary dysplasia or bronchiectasis.
- Known systemic or inflammatory diseases.
- 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).
- 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:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-04-2012
Enrollment:	75
Type:	Actual

Ethics review

Approved WMO

Date:	12-04-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC

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
Other	in aanvraag
CCMO	NL39477.018.12