The electronic nose in the discrimination of parent reported and doctor confirmed wheeze

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We hypothesize that expiratory VOC-analysis by electronic nose is capable of:1. Discriminating between asymptomatic infants and infants with respiratory wheeze.2. Discriminating between parent-reported and doctors-confirmed wheezy infants.The aim of...

Ethical review	Approved WMO
Status	Pending
Health condition type	Allergic conditions
Study type	Observational non invasive

Summary

ID

NL-OMON31929

Source
ToetsingOnline

Brief title
The electronic nose in the assesment of wheeze

Condition

- Allergic conditions
- Lower respiratory tract disorders (excl obstruction and infection)

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, Electronic nose, Exhaled Biomarkers, non-invasive, Respiratory Wheeze

Outcome measures

Primary outcome

The primary outcome of the study will be:

- the discrimination between the various clinically defined subgroups of

patients in a so-called *training-set.*

- the identification of newly recruited subjects from the same subgroups in a

so-called *validation-set*.

Secondary outcome

not-applicable

Study description

Background summary

Population studies have shown that 1 in 3 children have more than one episode of parent-reported wheezing before the age of 3 years. Especially the confirmation of this wheeze by a physician appears to be associated with the development of asthma and persistence of asthmatic symptoms beyond childhood. Pre-school children with confirmed wheeze appear to already exhibit the major histological features of asthma in the bronchial mucosa. Recent studies have shown that non-invasive molecular pattern recognition of volatile organic compounds (VOCs) in exhaled air is capable of discriminating between asthmatic children and controls. An electronic nose is an innovative method of analysing these VOCs real-time. Therefore, our current aim is to assess the potential of non-invasive exhaled breath profiling by electronic nose in sub-phenotyping infants with respiratory wheeze.

Study objective

We hypothesize that expiratory VOC-analysis by electronic nose is capable of:
1. Discriminating between asymptomatic infants and infants with respiratory wheeze.

2. Discriminating between parent-reported and doctors-confirmed wheezy infants.

The aim of this study is to address this hypothesis by integrating the clinical profiles and exhaled smell prints in infants with wheeze in a case-control, cross-sectional study.

Study design

The study has a case-control, cross-sectional design comparing infants with confirmed wheeze, with parent-reported wheeze and age-matched healthy children. The study consists of two phases:

Phase1: Trainingset: All children with parent-reported wheeze will be seen. The wheezing will be assessed by a qualified lung-physician and the exhaled air will be analyzed by the electronic nose. Additionally a group of healthy children will be included.

Phase2: Validation set: The sensitivity, specificity, negative and positive predictive value of the classification algorithms developed on basis of these children will be examined by detecting and monitoring disease in prospectively enrolled subjects on basis of an intention to diagnose.

Study burden and risks

The collection of expiratory air is totally non-invasive and thus without any health risk. This was comfirmed by pilot studies.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Patients:
Informed consent obtained from parents
age between 0 and 2 years;Healthy controls:
Informed consent obtained from parents
age between 0 and 2 years

Exclusion criteria

Patients:
Present metabolic or syndrom disorder
Underlying respiratory tract disease, like congenital airway abnormalities, cystic fibrosis, primary ciliary dyskinesia, bronchopulmonary dysplasia or bronchiectasis;Healthy controls:
Present metabolic or syndrome disorder
Respiratory tract disease

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:	Pending
Start date (anticipated):	01-08-2008
Enrollment:	105
Type:	Anticipated

Ethics review

Approved WMO

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
CCMO	NL23623.018.08