An electronic nose in infants with respiratory wheeze.

No registrations found.

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

Summary

ID

NL-OMON21823

Source
NTR

Brief title
Wheezy Infants study

Health condition

electronic nose, wheezing in infants

Sponsors and support

Primary sponsor: Academic Medical Center (AMC), Department of Pulmonology, Emma Children’s Hospital, Department of Pediatric Respiratory Medicine
Source(s) of monetary or material Support: Netherlands Asthma Foundation

Intervention

Outcome measures

Primary outcome

Discriminating between various clinically difined subgroups of patients in a so-called trainingset.

Identification of newly recruited subjects from the same subgroups in a so-called validation

set.

Secondary outcome

none

Study description

Background summary

Rationale:

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.

Hypothesis:

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.

Methods and Analysis:

One hundred five children (< 3 years) will be included: 35 children with confirmed wheeze, 35 children with parent-reported wheeze (not confirmed by a physician) and 35 healthy controls. Two exhaled breath samples of each child will be analysed by means of discriminant analysis on principal component reduction.

Relevance:

- This study evaluates the potential of a non-invasive electronic nose in objectively identifying a subgroup of infants with respiratory wheeze who are at risk of developing asthma.

-The true incidence of asthma in these high-risk children will need to be established by a separate prospective follow-up study.

Sampling:
Children will breathe normally through a face-mask into a modified Babyhaler®, with reversed valve systems (see figure 1). This allows tidal inspiration of room air and tidal expiration into the Babyhaler®. During tidal breathing the eNose will continuously sample air through a tube connected to the modified Babyhaler®

Study objective

We hypothesize that expiratory Volatile Organic Compounds analysis by an electronic nose is capable of discriminating between asymptomatic infants and infants with respiratory wheeze.

Study design

- measurements take place in a single visit.

Intervention

None; diagnostic study:

One hundred five children (< 3 years) will be included: 35 children with confirmed wheeze, 35 children with parent-reported wheeze (not confirmed by a physician) and 35 healthy controls. Two exhaled breath samples of each child will be analysed by means of discriminant analysis on principal component reduction.

Contacts

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Eligibility criteria

Inclusion criteria

1. <3 years

2. Parent-reported/ physician-reported wheeze

Exclusion criteria

1. >3 years

2. Metabolic, genetic or syndromal disorders

3. Inflammatory diseased
underlying respiratory tract disease

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	03-12-2008
Enrollment:	105
Type:	Anticipated

Ethics review

Positive opinion

Date:	28-11-2008
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	NL1496

Register	ID
NTR-old	NTR1566
Other	MEC AMC : 08/153
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A