An electronic nose in infants with respiratory wheeze.

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21823

Bron
NTR

Verkorte titel
Wheezy Infants study

Aandoening

electronic nose, wheezing in infants

Ondersteuning

Primaire sponsor: Academic Medical Center (AMC), Department of Pulmonology, Emma Children’s Hospital, Department of Pediatric Respiratory Medicine
Overige ondersteuning: Netherlands Asthma Foundation

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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®

Doel van het onderzoek

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

Onderzoeksopzet

- measurements take place in a single visit.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. <3 years

2. Parent-reported/ physician-reported wheeze

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. >3 years

2. Metabolic, genetic or syndromal disorders

3. Inflammatory diseased
underlying respiratory tract disease

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	03-12-2008
Aantal proefpersonen:	105
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	28-11-2008
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1496
NTR-old	NTR1566
Ander register	MEC AMC : 08/153
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A