The diagnostic accuracy of exhaled breath fingerprinting by eNose in diagnosing asthma and atopy.

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We postulate that exhaled breath sampling by an electronic nose can distinguish and adequately identify smell-prints from: 1. Atopic patients without airway obstruction 2. Non-atopic patients without airway obstruction 3. Atopic patients with...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22125

Bron
NTR

Verkorte titel
eNose CMH

Aandoening

English: Asthma. Atopy. Wheezing. exhaled breath analysis.
Dutch: Astma. Atopie. Piepende ademhaling. Uitademingslucht analyse.

Ondersteuning

Primaire sponsor: AMC Medical Center, Dept. of Respiratory Medicine, Amsterdam, The Netherlands.
Central Military Hospital, Ministery of Defence, Utrecht, The Netherlands.
Overige ondersteuning: Netherlands Asthma Foundation.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Electronic nose smellprint of a vital capacity volume breath sample.

Toelichting onderzoek

Achtergrond van het onderzoek

Background and rationale:
Diagnosing and monitoring of asthma is based on its clinical presentation and repeated measurement of lung function. However, these tests are time-consuming and not widely applicable. Furthermore, differential diagnosis, (sub)phenotyping and monitoring of asthma remain difficult, which hinders clinical management, especially in primary care.

Simple and fast diagnostic methods in asthma are therefore needed, and improving accuracy and cost-effectiveness of diagnosing and monitoring asthma can contribute to improved management of the disease.

Using exhaled air as the source for measuring biomarkers is attractive because it is noninvasive and allows repeated sampling. Heterogeneity in asthma is also likely to be reflected in the composition of the exhaled air, which is known to contain thousands of volatile organic compounds (VOCs) that are derived from various metabolic pathways taking place in the lung and elsewhere in the body. These VOCs, alone or in combination, can potentially be used as biomarkers for the disease in general and more specifically, for its several subclasses.

Electronic nose (eNose) technology is based on an array of sensors reacting to the many volatile organic compounds (VOC's) in breath, combined with pattern recognition algorithms. Recently, Dragonieri et al demonstrated that an electronic nose was able to distinguish the smell-prints of exhaled breath from patients with asthma and healthy controls (JACI 2008).

The current study aims to estimate the diagnostic accuracy of exhaled breath measurement using the electronic nose in asthma and atopy, following the STARD criteria.

Hypothesis:

We postulate that exhaled breath sampling by an electronic nose can distinguish and adequately identify smell-prints from:

1. Atopic patients without airway obstruction

2. Non-atopic patients without airway obstruction

3. Atopic patients with airway obstruction

4. Non-atopic patients with airway obstruction

Aim of the study:

To estimate the diagnostic accuracy of exhaled breath measurement using the electronic nose in asthma and atopy.

Outcome parameters:

The primary outcome parameter is the smell-print provided by the electronic nose.

Subjects:

Patients (>16 years old) referred to the department of Pulmonology of the Central Military Hospital (CMH), Utrecht for evaluation of asthma and/or atopy will be included.

Design:
The study comprises prospective enrollment of possible new patients from a population suspect for asthma and of healthy controls.
In this validation phase of the study, the diagnostic accuracy of the electronic nose is determined in a screening setting for asthma in population with an intention to diagnoses. Subsequently, the specificity and negative predictive value and the sensitivity and positive predictive value will be calculated in relation to the gold standard phenotypes.

Methods of measurement:
Electronic nose: the Cyranose 320 (Smith Detections, Pasadena, Ca, USA), a handheld portable chemical vapor analyzer, containing a nanocomposite sensor array with 32 polymer sensors and The DiagNose (C-it, Zutphen, Nederland), a handheld portable chemical vapor analyzer, containing an array of three microhotplate type metaloxide sensors in conjunction with factory calibrated temperature and relative humidity sensors. Patients will breathe normally through a mouthpiece, connected to a three-way non-re-breathing valve and an inspiratory VOC-filter (A2, North Safety, NL) for 5 minutes. After a single deep inspiration the patient exhales a vital capacity volume into a Tedlar bag connected to the expiratory port. Within 30 minutes the electronic nose will be connected to the Tedlar bag, followed by 1 minute sampling of the exhaled air.

Skin prick test/RAST: allergy testing.

Spirometry: prebronchodilator spirometry according to ERS/ATS recommendations.

Exhaled NO: using the Niox Aerocrine according to the ATS recommendations (ATS NO).

Exhaled CO: using a Bedfont Micro Smokerlyzer (Bedfont Scientific LTD, Rochester, England) (Middleton, Morice).
Bronchial responsiveness by histamine challenge according to ERS/ATS recommendations.

Symptoms:
Questionnaires for assessing symptoms of asthma and for co-morbidity will be used.

Analysis:
The smell prints will be analysed by off-line learning software (Dept. Medical Statistics, AMC, LUMC). Double cross-validatory implementation of linear discriminant analysis on principal component reduction will be performed using SPSS software.

Study management:
Primary investigator: Niki Fens, MD, Prof. Peter J Sterk, MD, PhD, Noël Schlösser, MD.
Ethics: The LUMC and AMC Medical Ethics Committees have approved the protocol entitled: 'The electronic nose in the diagnostic assessment of airway disease' (05/119 LUMC, 07/153 AMC).
The Medical Ethics Committee of the Ministry of Defence (Central Military Hospital) has approved the protocol.

Doel van het onderzoek

We postulate that exhaled breath sampling by an electronic nose can distinguish and adequately identify smell-prints from:

1. Atopic patients without airway obstruction

2. Non-atopic patients without airway obstruction

3. Atopic patients with airway obstruction

4. Non-atopic patients with airway obstruction

Onderzoeksopzet

All measurements will take place in a single visit of approx. 1 1/2 hour.

Onderzoeksproduct en/of interventie

None: diagnostic study.

Contactpersonen

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. ≥ 17 years

2. Referred to the Central Military Hospital, dept. of Pulmonology for evaluation of asthma and/or atopy.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. < 17 years

2. Present upper respiratory infection or common cold, or in the past 2 weeks

3. Asthma exacerbation < 4 weeks

4. Present dental problems:

paradontitis, recent extraction of tooth (< 2 weeks)

5. Chronic tonsillitis or sinusitis

6. Eating/drinking/smoking/brushing teeth/chewing gum/mint < 3 hours before eNose measurement

7. Use of long-acting inhaled ¦Â-agonists < 24 hours and/or use of short-acting ¦Â-agonists < 12 hours and/or use of inhaled corticosteroids < 24 hours

8. Known thyroid dysfunction and/or use of Levothyroxine

9. Known diagnosis of diabetes mellitus

10. Failure to complete eNose measurement

11. Not willing to participate in the study or lack of understanding

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Enkelblind

Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	12-08-2008
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	10-08-2008
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	NL1339
NTR-old	NTR1398
Ander register	: CMH2008000627-037
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A