Breath testing for asthma and COPD.

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We postulate that exhaled breath sampling by an electronic nose can adequately identify asthma or COPD in breathprints from patients with an intention to diagnose.

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

Samenvatting

ID

NL-OMON28944

Bron
NTR

Verkorte titel
IDeNose

Aandoening

asthma, COPD, diagnostic accuracy, STARD, intention to diagnose
astma, COPD, diagnostische waarde, STARD, verdenking diagnose

Ondersteuning

Primaire sponsor: Academic Medical Centre Amsterdam
Overige ondersteuning: Netherlands Asthma Foundation, grant no 3.2.06.17

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary outcome parameter is the breathprint provided by the electronic nose.

Toelichting onderzoek

Achtergrond van het onderzoek

Background and rationale:

Diagnosing and monitoring of asthma and COPD is based on 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 obstructive lung diseases remain difficult, which hinders clinical management, especially in primary care.

Simple and fast diagnostic methods in asthma and COPD are therefore needed, and improving accuracy and cost-effectiveness of diagnosing and monitoring can contribute to improved management of the diseases.
Using exhaled air as the source for measuring biomarkers is attractive because it is noninvasive and allows repeated sampling. Heterogeneity in asthma and COPD 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 obstructive airways diseases 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, Fens et al demonstrated that an electronic nose was able to distinguish the breathprints from patients with asthma, COPD and smoking and non-smoking healthy controls (AJRCCM 2009). In an external validation study, asthma and COPD could be diagnosed with high sensitivity and specificity in patients with 'classic' disease and in patients with persistent airways obstruction with either COPD or asthma [Fens et al, submitted].

The current study aims to estimate the diagnostic accuracy for asthma and COPD of exhaled breath measurement using the electronic nose in patients with an intention to diagnose, following the STARD criteria.

Doel van het onderzoek

We postulate that exhaled breath sampling by an electronic nose can adequately identify asthma or COPD in breathprints from patients with an intention to diagnose.

Onderzoeksopzet

Visits to outpatient and pulmonary function clinics as scheduled for routine diagnostic workup. Measurement of primary outcome (electronic nose) will be performed once, preferably at the first visit.

Onderzoeksproduct en/of interventie

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. 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.

Diagnostic work-up for asthma or COPD.

According to usual care.

At least pre-bronchodilator spirometry and symptoms.

Skin prick test/RAST: Allergy testing.

Spirometry: Pre- and postbronchodilator spirometry according to ERS/ATS recommendations.

Exhaled NO: Using the Niox Aerocrine or Niox Mino according to the ATS recommendations (ATS NO).

Bronchial responsiveness by histamine or methacholine challenge according to ERS/ATS recommendations.

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients (>16 years old) getting a diagnostic work-up for asthma or COPD in the Academic Medical Centre (Amsterdam) will be included in the study;

2. Differential diagnosis of asthma, COPD, obstructive lung disease;

3. Clinical evaluation for reversibility (FEV1), airway hyperresponsiveness, airway obstruction.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Known current diagnosis of asthma and/or COPD.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	17-05-2010
Aantal proefpersonen:	80
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	11-05-2010
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	NL2197
NTR-old	NTR2321
Ander register	METC AMC : 07/153
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
Previous publication on subject:
Fens et al. Am J Respir Crit Care Med. 2009 Dec 1;180(11):1076-82.