The electronic nose as a diagnostic tool in the discrimination of COPD and controls

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We postulate that exhaled breath sampling by an electronic nose can distinguish: 1. Patients with COPD GOLD stadium 2-3, who do not use inhaled corticosteroids 2. Patients with COPD GOLD stadium 2-3, who use inhaled corticosteroids 3. Patients...

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

Samenvatting

ID

NL-OMON23287

Bron
NTR

Verkorte titel
The electronic nose in the discrimination of COPD and controls

Aandoening

COPD, Asthma, wheezing, airway inflammation, smoking

Ondersteuning

Primaire sponsor: Academic Medical Center Amsterdam, The Netherlands
Overige ondersteuning: Netherlands Asthma Foundation
grand no 3.2.06.17

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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. When exposed to a gas mixture, the sensors will swell and thus change the electrical conductance, resulting in a unique smell-print. These measurements are stored in an on-board database and can be analyzed by the pattern recognition software as well as by offline statistics software (see analysis section).
Breathing maneuver: 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.
Sampling: Within 30 minutes the electronic nose will be connected to the Tedlar bag, followed by 1 minute sampling of the exhaled air.
Measurements as described above will be performed in duplo.

Toelichting onderzoek

Achtergrond van het onderzoek

Background: Recently, ‘omics’ techniques became available, based on an empirical approach of analysis of the overall molecular characteristics of biological samples, including exhaled breath. By the use of arrays of sensors, combined with pattern recognition algorithms, a sample of breath can be analyzed for its volatile organic compounds by an electronic nose, resulting in a specific ‘smell-print’. The usage of the electronic nose in COPD can potentially improve diagnostics and monitoring.

Hypothesis: We postulate that exhaled breath sampling by an electronic nose can distinguish the following groups of patients: patients with COPD (GOLD stadium II or III; smoking or ex-smoking; using or not using inhaled corticosteroids), smoking and non-smoking asymptomatic controls and asthma patients.

Aim: The aim of this study is to provide evidence that the electronic nose is able to discriminate between the groups that are mentioned above in a cross-sectional study.
Outcome parameters: The primary outcome parameter is the smell-print provided by the electronic nose, together with the results of the on-board and offline statistical analysis.

Subjects: A minimum of ten subjects in each category mentioned above are required. All patients and controls will be 40-75 years.

Design: Cross-sectional case-reference design in order to train the electronic nose in discriminating between several subgroups of COPD, controls and asthma.

Methods: Electronic nose: the Cyranose 320 (Smith Detections, Pasadena, Ca, USA). When exposed to a gas mixture, the sensors will swell and thus change the electrical conductance, resulting in a unique smell-print. These measurements can be analyzed by the pattern

recognition software as well as by offline statistics software.

Breathing maneuver: 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. The patient exhales a vital capacity volume into a Tedlar bag connected to the expiratory port.
Sampling: 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: using a panel of 10 common airborne allergens.

Spirometry and reversibility: performed by standardized ATS/ERS methods.

Bronchial responsiveness: by methacholine challenge using a standardized ATS/ERS procedure.

CO-diffusion capacity: single-breath, breath holding technique.

Symptoms: validated questionnaires for assessing symptoms of COPD, smoking habits and for co-morbidity.

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).

Doel van het onderzoek

We postulate that exhaled breath sampling by an electronic nose can distinguish:

1. Patients with COPD GOLD stadium 2-3, who do not use inhaled corticosteroids

2. Patients with COPD GOLD stadium 2-3, who use inhaled corticosteroids

3. Patients with COPD GOLD stadium 2-3, who are smoking

4. Patients with COPD GOLD stadium 2-3, who are not smoking

5. Asymptomatic controls who are smoking (>10 Packyears (PY))

6. Non-smoking asymptomatic controls (< 5 PY)

7. Non-smoking patients with allergic asthma (<5 PY), who use inhaled corticosteroids

Onderzoeksopzet

All measurements take place in a single visit for COPD patients.

In addition, controls and asthma patients perform a metacholine test on a separate day within one month.

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. COPD patients

2. A minimum of ten patients 40-75 years with moderate to severe COPD:

• Smoking 10 cigarettes/day, > 10 pack years or

• Non-smoking (> 10 pack years, > 12 months)

• Matching GOLD severity step 2:

o Presence of symptoms of

 Shortness of breath typically developing on exertion

 Occasional occurrence of cough and sputum production

o Postbronchodilator 50% < FEV1 < 80% predicted

o Postbronchodilator FEV1/FVC < 0.70

• Matching GOLD severity step 3:

o Presence of symptoms of

 Greater shortness of breath

 Reduced exercise capacity

 Fatigue and

 Repeated exacerbations that affect quality of life

o Postbronchodilator 30% < FEV1 < 50%

o Postbronchodilator FEV1/FVC < 0.70

Controls

A minimum of ten asymptomatic age-matched > 40 years controls:

• Non-smoking (< 5 pack-years, > 12 months) and

• Smoking (> 10 pack-years, >10 cigarettes/day) and

• Ex-smoking (> 10 pack years, > 12 months)

• A negative history on lung diseases

• A negative history on any other acute or chronic illness

• Prebronchodilator FEV1 > 80% predicted

• FEV1/FVC > 0.70

• Absence of bronchial hyperresponsiveness demonstrated by PC20 > 4 mg/ml

• Negative skin prick test or RAST to common environmental allergens

• Absence of symptoms of

o Shortness of breath

o Chest pains

o Cough

o Sputum production

o Reduced exercise capacity

o Fatigue

Asthma

A minimum of ten asthmatic patients > 18 years:

• Non-smoking (< 5 pack-years, > 12 months) and

• A negative history on other lung diseases than asthma

• A negative history on any other acute or chronic illness than asthma

• Prebronchodilator FEV1 > 50% predicted

• Presence of bronchial hyperresponsiveness demonstrated by PC20 < 8 mg/ml

• Positive skin prick test or RAST to one or more common environmental allergens

• Chronic use of inhaled corticosteroids

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Two or more of the following:

• Severe cardiovascular disease, history or present

• Myocardial infarction

• Coronary bypass surgery

• CVA

• Pulmonary embolism and deep venous thrombosis

• Heart failure

• Diabetes mellitus (documented in the past)

• Hypercholesterolaemia (documented in the past)

• Systemic inflammatory disease

• Cancer diagnosed and treated within 5 years, or known incomplete remission if earlier

• Any active inflammation

One or more of the following:

• The use of oxygen.

• For COPD-patients: GOLD-stadium I or IV.

• For controls: Reversibility in FEV1 by 400 ug of inhaled salbutamol > 12 % pred. (7)

• For asthma patients: the use of oral corticosteroids

• History of other pulmonary diseases or abnormalities eg tuberculosis, bronchiectasis, asthma, lung cancer, sarcoidosis

• Presence or recent history (4 weeks) of paradontitis

• History of upper or lower respiratory infection in the past 4 weeks.

• For patients: Exacerbation in the past 8 weeks

The definition of an exacerbation of COPD will follow the criteria by Anthonisen et al (6). This includes two or more of the following symptoms: worsening dyspnoea, increased sputum purulence, increased sputum volume, or one of these plus one of: upper respiratory tract infection during the past 5 days, fever without other cause, increased wheeze, increased cough or increased heart or respiratory rate by more than 20%.

• The presence of right-sided heart failure as indicated by physical examination.

• Inhalation medication < 12 hours (short-acting bronchodilation) or < 24 hours (long-acting) or < 3 hours inhaled corticosteroids

• Antihistamines, theofylline, and antibiotic use in the past 2 days

• Eating (including chewing gum), drinking, smoking, brushing teeth < 3 hours before measurements

• Bad technique in previous lung function tests

• Lack of comprehension of the study and measurements

• Pregnancy

• Hyper- or hypothyroid function or use of Levothyroxine

• Renal insufficiency

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	01-08-2007
Aantal proefpersonen:	120
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	16-04-2008
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	NL1237
NTR-old	NTR1282
Ander register	METC AMC : 07/153
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten

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