An electronic nose in the screening for COPD in an at risk population of (ex-)smokers.

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We postulate that exhaled breath sampling by an electronic nose can adequately identify newly presented patients with COPD in an at risk population ((ex-)smokers), regardless of symptoms.

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

Samenvatting

ID

NL-OMON20180

Bron
NTR

Verkorte titel
Nelson eNose study

Aandoening

COPD, smoking

Ondersteuning

Primaire sponsor: Academic Medical Center
University of Amsterdam
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Meibergdreef 9
1105 AZ Amsterdam
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University Medical Center Utrecht
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The Nelson Study Group (Nederlands-Leuvens Longkanker Screeningsonderzoek).
Overige ondersteuning: Netherlands Asthma Foundation grant no 3.2.06.17

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Electronic nose smellprint of a vital capacity volume breath sample.

Toelichting onderzoek

Achtergrond van het onderzoek

Background: A high proportion of COPD is not recognized and remains undiagnosed in the smoking community. By means of the recent introduction of ‘electronic noses’, the sampling of exhaled breath and its volatile organic compounds has become readily available. The usage of the electronic nose in COPD can potentially facilitate diagnostics and monitoring by reducing measurement time as compared to spirometry. Early diagnosis of COPD can potentially be improved by simply sampling exhaled breath from current smokers.

Hypothesis: We postulate that exhaled breath sampling by an electronic nose can adequately identify newly presented patients with COPD in an at risk population ((ex-)smokers), regardless of symptoms.

Aim: The aim of this study is to provide evidence that the electronic nose is able to identify COPD patients in a population of (ex-)smokers. The sensitivity, specificity, positive and negative predictive values will be calculated in relation to the GOLD standard phenotypes.

Subjects: Individuals, (ex-)smoking adults, participating in the Nelson Study will be assigned to a ‘prediction-set’.

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. 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.

Spirometry and reversibility: performed by standardized ERS methods.

CO-diffusion capacity: will be measured by a single-breath, breath holding technique.

Symptoms: validated questionnaires for assessing symptoms of COPD and for co-morbidity will be used.

Analysis: The analysis will be performed blinded in relation to all other tests in the patients and includes principal component analysis of the 32 signals, together with canonical discriminant analysis.

Ethics: The LUMC, AMC and UMCU 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 adequately identify newly presented patients with COPD in an at risk population ((ex-)smokers), regardless of symptoms.

Onderzoeksopzet

All measurements take place in a single visit.

Onderzoeksproduct en/of interventie

None: diagnostic study.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. > 40 years

2. Smoking or ex-smoking

3. > 20 pack years

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Failure to complete eNose measurement

2. 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:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	14-02-2008
Aantal proefpersonen:	250
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	21-04-2008
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	NL1240
NTR-old	NTR1285
Ander register	AMC : 08/101
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A