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

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20180

Source
NTR

Brief title
Nelson eNose study

Health condition

COPD, smoking

Sponsors and support

Primary sponsor: Academic Medical Center
University of Amsterdam
Dept. Pulmonology, F5-260
Meibergdreef 9
1105 AZ Amsterdam
The Netherlands

University Medical Center Utrecht
University of Utrecht
Dept. Pulmonology
Heidelberglaan 100
3584 CX Utrecht
The Netherlands

The Nelson Study Group (Nederlands-Leuvens Longkanker Screeningsonderzoek).
Source(s) of monetary or material Support: Netherlands Asthma Foundation grant no 3.2.06.17

Intervention

Outcome measures

Primary outcome

Electronic nose smellprint of a vital capacity volume breath sample.

Secondary outcome

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

- CO diffusion capacity according to ERS/ATS recommendations

- Spiral CT scan of the thorax: presence and extent of emphesema

- Questionnaires to assess symptoms of COPD, co-morbidity and smoking status.

Study description

Background summary

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).

Study objective

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.

Study design

All measurements take place in a single visit.

Intervention

None: diagnostic study.

Contacts

Public
Clinical Research Fellow 'Electronic Nose'
Academic Medical Center (AMC)

University of Amsterdam
Department of Pulmonology
 F5-260
P.O.Box 22660
Niki Fens
Meibergdreef 9

1100 DD
Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5664359
Scientific
Clinical Research Fellow 'Electronic Nose'
Academic Medical Center (AMC)
University of Amsterdam
Department of Pulmonology
 F5-260
P.O.Box 22660
Niki Fens
Meibergdreef 9

1100 DD
Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5664359

Eligibility criteria

Inclusion criteria

1. > 40 years

2. Smoking or ex-smoking

3. > 20 pack years

Exclusion criteria

1. Failure to complete eNose measurement

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

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-02-2008
Enrollment:	250
Type:	Actual

Ethics review

Positive opinion

Date:	21-04-2008
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL1240
NTR-old	NTR1285
Other	AMC : 08/101
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A