Detection of lung cancer from exhaled air with e-Nose

No registrations found.

Ethical review	Positive opinion	
Status	Recruiting	
Health condition type	-	
Study type	Observational non invasive	

Summary

ID

NL-OMON23014

Source NTR

Health condition

Lung cancer

Sponsors and support

Primary sponsor: Medisch Spectrum Twente Enschede Source(s) of monetary or material Support: The eNose Company André Elands, CEO Industrieweg 85 7202 CA Zutphen M: 06-11625597 E: andre.elands@eNose.nl

Intervention

Outcome measures

Primary outcome

Detection of differences in patterns of exhaled breath in patients diagnosed with lung cancer from subjects with a rejected diagnosis of lung cancer and healthy subjects.

Secondary outcome

- Detection of different patterns of exhaled breath in different lung cancer stages.
- Detection of different patterns of exhaled breath in different types of lung cancer.

Study description

Background summary

There is not yet a quick test, nor a non-invasive method to identify subjects with lung cancer. The Aeonose[™] (electronic nose) is a diagnostic test device to detect patterns of volatile organic compounds (VOC's) in exhaled air. These VOC's are related to metabolic activities in the body. It is assumed that the disease-specific metabolic pathways may give rise to specific VOC patterns and therefore aid in the diagnostic process. Pilot studies have already indicated that electronic noses, consisting of an array of VOC-sensors, may be used to detect diseases in different diagnostic areas, including malignancies.

The aim of this study is to investigate whether the eNose can detect VOC patterns that distinguish between patients suspected for lung cancer with a confirmed histopathological diagnosis and patients suspected for lung cancer with a rejected diagnosis of lung cancer. Also, we want to compare VOC patterns of those with a confirmed diagnosis of lung cancer with healthy subjects without any suspicion for lung cancer.

Study objective

Can the eNose detect VOC patterns that distinguish between patients with and without lung cancer?

Study design

Lung cancer: yes or no. 1 measurement

Type of lung cancer: NSCLC or SCLC. 1 measurement

Stadium of lung cancer: TNM classification and staging. 1 measurement.

Intervention

Measurement of exhaled breath with an electronic nose.

Contacts

Public Deurningerstraat 54

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Eligibility criteria

Inclusion criteria

Subjects suspected for lung cancer:

- 1. Scheduled to undergo CT-scanning;
- 2. They have suspicion of lung cancer based on the one or more of the following points:
- a. Respiratory symptoms such as: haemoptysis, coughing, dyspnoea;

b. General symptoms that go with malignancy, such as: weight loss, nocturnal hyperhidrosis, fever, and/or loss of appetite;

- c. An anomalous chest X-ray;
- 3. Age \geq 40 years;
- 4. Smoker or ex-smoker.

Healthy subjects:

- 1. A negative history of chest symptoms, for example asthma, COPD, other respiratory
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conditions.

Exclusion criteria

Subjects suspected for lung cancer:

1. Subjects with other prior known malignancies;

2. Subjects with a history of upper or lower respiratory tract infection during the past 4 weeks prior to measurements which required pharmacological treatment with antibiotics or systemic corticosteroids.

Healthy subjects:

1. Subjects with known significant metabolic disease, such as: diabetes mellitus, liver failure or active liver disease, renal failure, haemodialysis or cardiac failure, because of possible (un)known effects on metabolism;

- 2. Subjects with known COPD;
- 3. Subjects with an underlying malignancy.

Study design

Design

Control: N/A , unknown	
Allocation:	Non-randomized controlled trial
Intervention model:	Parallel
Study type:	Observational non invasive

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-05-2015
Enrollment:	300
Туре:	Anticipated

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Ethics review

Positive opinion Date: Application type:

15-04-2015 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

RegisterIDNTR-newNL5029NTR-oldNTR5175OtherMETC Twente : K15-17

Study results