

Detection of lung cancer from exhaled air with e-Nose

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

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

Samenvatting

ID

NL-OMON23014

Bron

NTR

Aandoening

Lung cancer

Ondersteuning

Primaire sponsor: Medisch Spectrum Twente Enschede

Overige ondersteuning: The eNose Company

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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

Measurement of exhaled breath with an electronic nose.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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 conditions.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-05-2015

Aantal proefpersonen: 300
Type: Verwachte startdatum

Ethische beoordeling

Positief advies
Datum: 15-04-2015
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	NL5029
NTR-old	NTR5175
Ander register	METC Twente : K15-17

Resultaten