eNose analysis of air sampled by bronchoscopy.

Gepubliceerd: 30-08-2010 Laatst bijgewerkt: 15-05-2024

A diagnostic algorithm based on tumour-site specific volatile organic compounds (VOCs) enables improved discrimination of lung cancer patients and controles , compared to exhaled breath sampling.

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

Samenvatting

ID

NL-OMON25372

Bron
NTR

Verkorte titel
BronchoNose study

Aandoening

electronic nose
bronchoscopy
lung cancer
elektronische neus
bronchoscopie
longkanker

Ondersteuning

Primaire sponsor: Academic Medical Centre, Amsterdam
Overige ondersteuning: Academic Medical Centre, Amsterdam

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. The endobronchial VOC-profiles of tumour side and contralateral side in lung cancer patients;
2. Endobronchial VOC profiles in healthy subjects;
3. Exhaled breath VOC profiles in both patients and healthy subjects.

Toelichting onderzoek

Achtergrond van het onderzoek

Background of the study:

Various study's based on analysis of exhaled Volatile Organic Compounds (VOCs) have shown the diagnostic potential of exhaled breath analysis or 'Breatheomics' in detecting novel biomarkers of disease. eNose technology is based upon pattern-recognition of volatile organic compounds. This methodology does not allow to analyze specific VOCs but integratively to assess all VOCs and there relative interactions with the sensor array.

As of now it is unknown whether the lung cancer specific VOCs represent a more general effect on homeostasis of a developing neoplasm or originate from the site of the tumor itself as most of the identified components have been related to increased oxidative stress. A previous study by our group however showed that COPD and NSCLC have a different VOC-profile suggesting that tumor specific volatile organic compounds are present. VOCs originating from the tumor itself are most likely more specific for the tumor than the VOCs that originate from the increased oxidative stress on the body. Detection of tumor-site specific volatile organic compounds can increase our knowledge of pathophysiological changes that occur in developing lung cancer.

Objective of the study:

We hypothesize that a diagnostic algorithm based on tumor site-specific VOCs enables improved discrimination of lung cancer patients and controls compared to exhaled breath sampling.

Study design:

This will be a cross-sectional comparative study including 2 groups of subjects with one study

visit. During the study visit, subjects will perform eNose assessment of exhaled breath, followed by bronchoscopy including bronchoscopic eNose sampling.

Study population:

The study will include 2 groups of subjects:

Group 1: 40 Patients with a clinical suspicion of lung cancer, based on a pulmonary lesion on chest-X-ray and/or computed tomography (CT) of the thorax, in whom diagnostic bronchoscopy will be performed.

Group 2: 30 Subjects undergoing bronchoscopy for scientific reasons.

Primary study parameters/outcome of the study:

Tumour-specific VOC-pattern of endobronchial sampled air and exhaled breath.

Doel van het onderzoek

A diagnostic algorithm based on tumour-site specific volatile organic compounds (VOCs) enables improved discrimination of lung cancer patients and controles , compared to exhaled breath sampling.

Onderzoeksopzet

One visit. All measurements take place at the same day (exhaled breath and endobronchial air sampling followed by electronic nose analysis).

Onderzoeksproduct en/of interventie

1. Exhaled breath sampling;

2. Bronchoscopy.

Contactpersonen

Publiek

Meibergdreef 9

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Subjects with clinical suspicion of lung cancer, based on a unilateral pulmonary lesion on chest X-ray and/or computed tomography of the thorax, in whom diagnostic bronchoscopy will be performed;

2. Healthy volunteers undergoing bronchoscopy for scientific purposes.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. General contraindications for bronchoscopy;

2. Age < 18 years.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Factorieel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd

Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	09-04-2010
Aantal proefpersonen:	70
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	30-08-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 35103
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2378
NTR-old	NTR2485
CCMO	NL31826.018.10
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON35103

Resultaten

Samenvatting resultaten
N/A