eNose analysis of air sampled by bronchoscopy.

No registrations found.

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

Summary

ID

NL-OMON25372

Source
Nationaal Trial Register

Brief title
BronchoNose study

Health condition

electronic nose
bronchoscopy
lung cancer
elektronische neus
bronchoscopie
longkanker

Sponsors and support

Primary sponsor: Academic Medical Centre, Amsterdam
Source(s) of monetary or material Support: Academic Medical Centre, Amsterdam

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

N/A

Study description

Background summary

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.

Study objective

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.

Study design

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

Intervention

1. Exhaled breath sampling;

2. Bronchoscopy.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

1. General contraindications for bronchoscopy;

2. Age < 18 years.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Factorial
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	09-04-2010
Enrollment:	70
Type:	Anticipated

Ethics review

Positive opinion

Date:	30-08-2010
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 35103
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results

Summary results
N/A