Smellprints in lung Cancer; the role of ENose in diagnosis and Treatment (SCENT):
part 1. Differences in smellprints between patients with lung cancer and breast cancer

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Primairy objective: we will examine the difference in VOC pattern of exhaled air between patients with histology-confirmed diagnoses of non small cell lung cancer vs breast cancer. Secundairy objective: a. to confirm the potential of the electronic...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Breast neoplasms malignant and unspecified (incl nipple)
Study type	Observational non invasive

Summary

ID

NL-OMON35264

Source
ToetsingOnline

Brief title
eNose in lung cancer/SCENT study, part 1

Condition

- Breast neoplasms malignant and unspecified (incl nipple)
- Respiratory tract neoplasms

Synonym
breast cancer, lung cancer or bronchial carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Leeuwarden
Source(s) of monetary or material Support: stichting Longgeneeskunde Fryslan

Intervention

Keyword: breast cancer, electronic nose, exhaled breath, lung cancer

Outcome measures

Primary outcome

The primary outcome parameter is the difference in smellprints provided by

eNose between patients with lung cancer and breast cancer.

Secondary outcome

The secondary outcomes are:

- the difference in smellprints between women with and without breast cancer

- the difference in smellprints between patients with non-small cell lung

cancer and healthy controls

- the difference in smellprints between patients before and twice after

resection of the lung tumour (at 1 and 6 weeks post-resection)

Study description

Background summary

Lung and breast cancer are leading causes of cancer-related death, with a total of 400,000 new lung and breast cancer cases and more than 200,000 deaths from these cancers per year in the United States [1]. Although mortality in breast cancer has been reduced after the introduction of screening programs [2], the 5 years survival in lung cancer remains poor, largely due to the fact that most patients with lung cancer present already with advanced disease. Given this

poor prognosis, early detection of lung cancer is considered crucial to decrease mortality, and in particular non-invasive diagnostic strategies aimed at identifying biomarkers of lung cancer are of great interest.
During the last few years the analysis of exhaled breath has been proposed as a novel option for early detection of lung cancer. Exhaled breath contains a complex mixture of several hundreds of volatile organic compounds (VOCs). This could be established by gas chromatography and mass spectrometry (GC-MS). It has been shown that distinct biochemical markers have been found in the exhaled breath of patients with lung and breast cancer that could be discriminated from those of controls, suggesting that VOC analysis might be used as a non invasive marker of these cancers. However, the requirement of elaborative offline GC-MS analysis limited the further development of this diagnostic potential.
After the introduction of electronic noses, the sampling of exhaled breath and its VOC-pattern has become readily available, due to their ability to allow on-board analysis and discrimination of *smellprints* by composite nano-sensors arrays (*breatheomics*). This is based on pattern recognition without analyzing the individual molecular components, which potentially suffices for diagnostic objectives.
The first studies by a sensor array in detecting lung cancer have demonstrated promising diagnostic accuracy and recently Dragonieri and colleagues showed that VOC patterns analysed by an electronic nose discriminated patients with lung cancer from COPD patients as well as healthy controls, further emphasizing the importance of prospective studies focussing on the diagnostic value of electronic noses in lung cancer.
Although most of previous mentioned studies were able to discriminate between patients with and without a specific type of cancer (mainly lung and breast cancer), until now studies comparing markers in exhaled breath in patients with different cancer types are lacking. So, the question remains whether the discrimination that can be made by an electronic nose is based on changes in VOCs due to an organ-specific malignancy or might be related to metabolic changes due to cancer in general.
In the present study, we hypothesize that an electronic nose can discriminate the VOC pattern in exhaled breath between patients with lung cancer and breast cancer. Furthermore it is very interesting to investigate whether the VOC pattern changes after resection of the (lung)malignancy.

Study objective

Primairy objective: we will examine the difference in VOC pattern of exhaled air between patients with histology-confirmed diagnoses of non small cell lung cancer vs breast cancer.
Secundairy objective:
a. to confirm the potential of the electronic nose to distinguish the VOC patterns between patients with NSCLC and healthy controls and to assess its capacity to discriminate between women with and without breast cancer.
b. when the eNose demonstrates to be capable to distinguish the VOC patterns of patients with NSCLC and breast cancer, we will try to identify the distinct

biomarkers in the exhaled breath samples of both groups by using gaschromatography and mass spectrometry (GC MS)
c. to investigate whether the VOC pattern changes when resection of the lung cancer has been performed.

Study design

open observational, case-control study.
for the lung cancer resection group in addition a short longitudinal observatory study.

Study burden and risks

All persons, patients and controls, will visit the pulmonary function department once. They first will complete a questionnaire obtaining information about medical history, smoking history en actual medical condition. Then exhaled breath collection will take place after 5 min tidal breathing VOC filtered room air. Finally spirometry will be performed. Total time will not exceed 20 min.

Both groups (breast cancer and lung cancer) are chosen, because they are leading causes of death and both have much better perspectives when diagnosed at early stage. eNose technology might be of great value in the screening and monitoring of these two cancers.

Patients with lung cancer treated with surgical resection, also if they are candidates for adjuvant chemotherapy or radiotherapy, will perform two additional measurements: at the end of their post-operative period in the hospital (about 7-14 days post operation) and at 6 weeks (before other adjuvant therapy modalities if needed) at the outpatient department. These measurements will be performed as much as possible during the regular hospital visits.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1. all women (18-80 yr) suspected of having breast cancer, referred to the OPD specialised in the diagnostic work-up of breast abnormalities in our hospital will be asked to participate (intention-to-diagnose). The first 25 patients with histologically confirmed breast cancer will be included in the analysis.
2. all patients (18-80 yr) suspected of having lung cancer, referred to the pulmonary OPD in our hospital will be asked to participate (intention-to-diagnose). The first 25 patients with histologically confirmed non-small cell lung cancer will be included in the analysis.
3. 25 women without breast cancer, matched with breast cancer patients above for age and smoking history, will be randomly selected from the intention-to-diagnose cohort.
4. 25 healthy controls, matched with the lung cancer patients above for sex, age, and smoking history, will be recruited from visitors and personel of our hospital, of course on voluntary base.

Exclusion criteria

other pulmonary disease. diabetes mellitus. documented hypercholesterolemia. malignancy in past. Significant cardiovascular pathology. Presence of paradontitis, history of upper or lower respiratory tract infection in the past 4 weeks.
Pregnancy, eating (including chewing gum), drinking, smoking < 3 hours before measurements.

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-01-2009
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	15-12-2008
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	15-01-2010
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)
Approved WMO Date:	24-06-2010
Application type:	Amendment
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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
CCMO	NL25812.099.08