Smellprints in lung Cancer; the role of ENose in diagnosis and Treatment (SCENT):
part 2. Identification of patients with lung cancer and breast cancer.

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1. To determine the diagnostic accuracy of the electronic nose in the identification of lung cancer in new (referred for suspicion of lung cancer) patients based on the algorithm developed in the SCENT study part 1 (training-set).2. To determine the...

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-OMON32897

Source
ToetsingOnline

Brief title
eNose in lung cancer/SCENT study, part 2

Condition

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

Synonym
lung cancer or bronchial carcinoma/ breast cancer or mamma 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

Sensitivity, specificity, positive and negative predictive value of the eNose

combined with the statistical algorithm developed from the training-set in the

SCENT study part 1.

Secondary outcome

not applicable

Study description

Background summary

Lung and breast cancer are leading causes of cancer-related death. 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. Lung cancer is clinically divided into two sub-types, small cell lung cancer, (SCLC; 10-15% of lung cancer cases), and non-small cell lung cancer (NSCLC (subdivided into mainly adenocarcinoma and squamous cell carcinoma); 85-90% of cases). 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. The electronic noses based on pattern recognition without analyzing the individual molecular components might be sufficient for diagnostic objectives. In the present study we will use the results obtained in the SCENT study part 1 (*differences in smellprints between patients with non small cell lung cancer and breast cancer*). In that study the electronic nose will be trained to develop the algorithm to discriminate patients with confirmed diagnoses of non small cell lung cancer or breast cancer from controls. On the

condition that such a discriminating algorithm can be deduced from the results of part 1, in this study (part 2 of the SCENT study) we will test the hypothesis that smellprints can identify and classify newly presented patients prospectively into the categories of non small cell lung cancer (NSCLC) and breast cancer

Study objective

1. To determine the diagnostic accuracy of the electronic nose in the identification of lung cancer in new (referred for suspicion of lung cancer) patients based on the algorithm developed in the SCENT study part 1 (training-set).
2. To determine the diagnostic accuracy of the electronic nose in the identification of breast cancer in new (referred for suspicion of breast cancer) patients based on the algorithm developed in the SCENT study part 1 (training-set).

Study design

diagnostical 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.

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 (*mamma poli*) will be asked to participate (intention-to-diagnose).
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).

Exclusion criteria

Patients of whom it is not possible to make the diagnose lung cancer or breast cancer.
eating (including chewing gum), drinking,brushing teeth, smoking < 3 hours before measurements.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	22-01-2009
Enrollment:	300
Type:	Actual

Ethics review

Approved WMO Date:	30-12-2008
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)

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	NL25946.099.08
Other	volgt: aanvraagnr 4829: trialregister.nl