SCENT 1. Differences in smellprints between patients with lung cancer and breast cancer.

No registrations found.

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

Summary

ID

NL-OMON28095

Source
Nationaal Trial Register

Brief title
SCENT study

Health condition

eNose (electronische neus)
smell-print (geurprofiel)
lung cancer (longkanker)
breast cancer (borstkanker)
exhaled breath (uitademingslucht)

Sponsors and support

Primary sponsor: MCL (hospital)
Source(s) of monetary or material Support: MCL

Intervention

Outcome measures

Primary outcome

(Difference) in smell-prints between patients with lung cancer AND breast cancer.

Secondary outcome

1. Difference in smell-prints between patients with breast cancer and controls;

2. Difference in smell-prints between patients with lung cancer and controls;

3. Difference in smellprints between patients before and twice after resection of the lung tumour (at 1 and 6 week post-resection).

Study description

Background summary

In the present study 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.

As secondary aims, we intend 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. We also aim to investigate whether the VOC pattern changes when resection of the lung cancer has been performed.

Finally, 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).

Study design:

Cross-sectional case-control study.

Patient recruitment on base of intention to diagnose: See study population.

At the Pulmonary Function Department each participant will follow this sequence:

1. Questionnaire;

2. Exhaled breath collection;

3. Spirometry.

Study population:

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). 25 patients with histologically confirmed breast cancer without significant co-morbidity will be included in the analysis of the present study.

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). 25 patients with histologically confirmed non-small cell lung cancer without significant co-morbidity will be included in the analysis of the present study.

3. 25 women without breast cancer, matched with breast cancer patients (above) for age and smoking history without significant co-morbidity, will be selected from the intention-to-diagnose cohort.

4. 25 healthy controls, matched with the NSCLC patients (above) for sex, age, and smoking history, will be recruited from visitors and personnel of our hospital, of course on voluntary base.

Study objective

We hypothesize that an electronic nose can discriminate the VOC pattern in exhaled breath between patients with non small cell lung cancer (NSCLC) and breast cancer.

Study design

Baseline measurement when they are seen for the first time at the outpatient department. In case of resection of tumor 2 and 6 weeks post-operative also a measurement.

Intervention

N/A

Contacts

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Eligibility criteria

Inclusion criteria

Written informed consent obtained.

Lung cancer patients:

1. Adults 18-80 years;

2. Non small cell lung cancer (NSCLC).

Lung cancer controls:

1. Adults 18-80 years;

2. Matched for:

a. Age: age<50 yr, 50
b. Smoking status: current smoker or ex-smoker<3 months, ex-smoker>3 months.

c. Sex.

Breast cancer patients:

1. Women 18-80 years;

2. Breast cancer.

Breast cancer controls:

1. Women 18-80 years;

2. Matched for:

a. Age: age<50 yr, 50≤age≤70, 70
b. Smoking status: current smoker or ex-smoker<3 months, ex-smoker>3 months.

Exclusion criteria

1. Other known pulmonary diseases;

2. Other or former malignancy;

3. Pregnancy;

4. Diabetes mellitus (documented in the past);

5. Hypercholesterolaemia (documented in the past);

6. Significant cardiovascular disease;

7. Any infection (especially of the airways) in the last 4 weeks;

8. Paradontitis.

Study design

Design

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

Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	02-01-2009
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion

Date:	29-12-2008
Application type:	First submission

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
NTR-new	NL1533
NTR-old	NTR1604
Other	TPO : 579
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A