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

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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.

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

Samenvatting

ID

NL-OMON28095

Bron
Nationaal Trial Register

Verkorte titel
SCENT study

Aandoening

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

Ondersteuning

Primaire sponsor: MCL (hospital)
Overige ondersteuning: MCL

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type: Observationeel onderzoek, zonder invasieve metingen

Onderzoeksmodel:	Anders
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	02-01-2009
Aantal proefpersonen:	100
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	29-12-2008
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1533
NTR-old	NTR1604
Ander register	TPO : 579
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A