SCENT part 2. Identification of 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-OMON27863

Source

NTR

Brief title

SCENT

Health condition

smell-print electronic Nose exhaled breath lung cancer breast cancer

Sponsors and support

Primary sponsor: MCL

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

Intervention

Outcome measures

Primary outcome

Sensitivity, specificity, positive and negative predictive value of the eNose in detecting NSCLC or breast cancer.

Secondary outcome

Sensitivity, specificity, positive and negative predictive value of the eNose in detecting subtypes of NSCLC (adenocarcinoma or squamous cell carcinoma)

Study description

Background summary

On the condition that such a discriminating algorithm can be deduced from the results of part 1, in 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.

Objective:

- a. To determine the diagnostic accuracy of the electronic nose in establishing the sensitivity, specificity, positive and negative predictive value for detecting non small cell lung cancer in prospectively enrolled subjects (based on intention to diagnose in clinical practice);
- b. To determine the diagnostic accuracy of the electronic nose in establishing the sensitivity, specificity, positive and negative predictive value for detecting breast cancer in prospectively enrolled subjects (based on intention to diagnose in clinical practice).

Study design:

diagnostic study.

This comprises prospective enrolment of new patients with an 'intention to diagnose' in order to determine the diagnostic accuracy of the electronic nose in the identification of NSCLC or breast cancer.

Study population:

All patients (18-80 yr) referred to the outpatient department pulmonary diseases for suspicion of lung cancer and at the outpatient department of surgery for suspicion of breast cancer.

Main study parameters/endpoints:

Sensitivity, specificity, positive and negative predictive value of the eNose in detecting NSCLC or breast cancer.

Study objective

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 design

Baseline measurement before histologic diagnosis is made.

Intervention

N/A

Contacts

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Eligibility criteria

Inclusion criteria

All patients (18-80 yr) referred to the outpatient department pulmonary diseases for suspicion of lung cancer and at the outpatient department of surgery for suspicion of breast cancer.

Exclusion criteria

None, exept impossibillity to make a diagnosis or follow the instructions prior to the measurement.

Study design

Design

Study type: Observational non invasive

Intervention model: Other

Allocation: Non controlled trial

Control: N/A, unknown

Recruitment

NL

Recruitment status: Suspended Start date (anticipated): 02-01-2009

Enrollment: 300

Type: Anticipated

Ethics review

Positive opinion

Date: 29-12-2008

Application type: First submission

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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 NL1534 NTR-old NTR1606 Other TPO: 588

ISRCTN wordt niet meer aangevraagd

Study results

Summary results

N/A