Smellprints in lung Cancer; the role of ENose in diagnosis and Treatment (SCENT):
part 3. Acute effects on smellprints of chemotherapy in patients with lung cancer.

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1 The primary objective is to investigate whether the eNose can discriminate the smellprints obtained before and after 1 cycle of chemotherapy in patients with specific histological types of lung cancer (NSCLC: adenocarcinoma, squamous cell...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory tract neoplasms
Study type	Observational non invasive

Summary

ID

NL-OMON32493

Source
ToetsingOnline

Brief title
SCENT study, part 3

Condition

- Respiratory tract neoplasms

Synonym
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: chemotherapy, electronic nose, exhaled breath, lung cancer

Outcome measures

Primary outcome

- Difference in smellprints of exhaled breath provided by the eNose before and

after chemotherapy.

Secondary outcome

-ad a: difference in smellprints of exhaled breath provided by the eNose

between distinct subgroups of lung cancer (adenocarcinoma vs sqamous cell

carcinoma vs SCLC)

-ad b: relationship between smellprints and stage of lung cancer or SUV on

18FDG-PET (see objectives).

-ad c: relationship between smellprints and tumour response classified

according to the RECIST [3] criteria

Study description

Background summary

Lung cancer is one of the leading causes of cancer related death worldwide.
This disease 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). Most patients with NSCLC present with advanced, often incurable,

disease (stages IIIA, IIIB and IV) at the time of diagnosis. For these patients as well as for patients with SCLC the standard treatment is chemotherapy, with or without radiotherapy. The response on chemotherapy, however, varies between individual patients. Therefore, the challenges for optimal treatment in these patients lay in the possibility of predicting chemotherapy response in the individual patient, developing customized chemotherapeutic combinations and limiting severe side effects.
During the last few years the analysis of exhaled breath has been proposed as a novel option for detection and management of lung cancer. Exhaled breath contains a complex mixture of several hundreds of volatile organic compounds (VOCs). Many VOCs, principally alkanes and benzene derivates, have been identified in breath from patients with lung cancer and changes in individual VOCs have been observed after surgical removal of the tumour, suggesting that VOCs in exhaled breath might reflect tumour activity,
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. The first studies using eNose technology in detecting lung cancer have demonstrated promising diagnostic accuracy and the intriguing possibility of an easily available panel of biomarkers (smellprint) reflecting tumour activity, emphasize the importance of prospective studies focussing on the value of electronic noses not only for diagnostic but also for predictive or follow up purposes.
Therefore in the present study, we hypothesize that chemotherapy-induced changes in exhaled metabolites in lung cancer can be detected by changes in VOC profiles (smell-prints) measured by the eNose.

Study objective

1 The primary objective is to investigate whether the eNose can discriminate the smellprints obtained before and after 1 cycle of chemotherapy in patients with specific histological types of lung cancer (NSCLC: adenocarcinoma, squamous cell carcinoma and SCLC)

2 The secondary objectives are:
a) To investigate whether the eNose can discriminate between the baseline smellprints of patients with different histological types of lung cancer (NSCLC: adenocarcinoma, squamous cell carcinoma and SCLC)
b) To investigate whether the pre-chemotherapy smellprint is related to:
i. the stage of the disease according to the stage grouping of the Mountain classification (NSCLC) [21] or division into LD or ED (SCLC) [2].
ii. metabolic activity of the disease as assessed by Standard Uptake Value (SUV) on PET-CT scan.
c) To investigate whether the potential change in smellprint after 1 cycle of chemotherapy is related to tumour response (determined after the second cycle

of chemotherapy) according to the RECIST criteria.

Study design

prospective, observational study

Intervention

first cycle of chemotherapy for lung cancer. Patients were already scheduled for this treatment after staging work-up.
NSCLC: cisplatin/gemcitabin
SCLC: cisplatin/etoposide

Study burden and risks

All patients will visit the pulmonary function department 3 times. At each visit 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 per visit will not exceed 20 min.

these lung cancer groups are chosen, because they are the most common subtypes and at this moment prediction who will benefit most by chemotherapy (individual-level) is not possible. We might learn in a non invasive manner more about tailoring therapy.

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

-Informed consent is obtained.
-newly diagnosed adenocarcinoma or squamous cell carcinoma stage IIIA, IIIB or IV or small cell lung cancer)
-Adults 18-80 years.
-scheduled for chemotherapy as first part of the treatment:
Cisplatin/Gemcitabine (NSCLC) and Cisplatin/Etoposide (SCLC)

Exclusion criteria

-Previous chemotherapy
-unable to evaluate response with the RECIST criteria.
-unable to follow the instructions for the eNose measurement
-eating, drinking and smoking < 3 hours prior to measurement

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):	26-01-2009
Enrollment:	75
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	NL25947.099.08
Other	volgt aanvrnr:4830 trialregistr.nl