SCENT
part 3. Acute effects on smellprints of chemotherapy in patients with lung cancer.

No registrations found.

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

Summary

ID

NL-OMON27548

Source
Nationaal Trial Register

Brief title
SCENT (study 3)

Health condition

electronic nose
smell-print
exhaled breath
lung cancer
chemotherapy

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

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).

Secondary outcome

The secondary objectives are:

1. 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);

2. To investigate whether the pre-chemotherapy smellprint is related to:

a. the stage of the disease according to the stage grouping of the Mountain classification (NSCLC) [21] or division into LD or ED (SCLC) [2];

b. metabolic activity of the disease as assessed by Standard Uptake Value (SUV) on PET-CT scan;

3. 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 description

Background summary

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.

Objectives:

1. The primary objective of this study 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 baseline smellprint (pre chemotherapy) 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) as assessed by changes in tumour size and classified according to the RECIST criteria.

Study design:

prospective, observational study.

Scheme:

0 1 15 22 (day)
I___I chemotherapyI_____I_____I
1 2 3 (visit)

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

1. questionnaire;

2. exhaled breath collection;

3. spirometry.

1. STUDY POPULATION;

1.1 Population;

Patients with newly diagnosed adenocarcinoma or squamous cell carcinoma stage IIIA, IIIB or IV or small cell lung cancer who are scheduled for their first cycle of chemotherapy at the department of pulmonary diseases.

1.2 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).

1.3 Exclusion criteria;

-Previous chemotherapy;

-unable to evaluate response with the RECIST criteria;

-unable to follow the instructions for the eNose measurement.

1.4 Sample size calculation.

This is an observational study with descriptive statistic analysis.
The sample size was calculated for the primary question whether the eNose measurements (smellprints) change during the first chemotherapy cycle. Our intention is to have at least 80% power for the case that the mean difference between the eNose measurements at baseline and after the first chemotherapy cycle is 0.5 SD or more.

This is achieved when we include 25 patients per group or more.

Study objective

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 design

Day 1(before first cycle of chemotherapy), day 15 (after chemo) and day 22 (just before second chemo).

Intervention

N/A

Contacts

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Eligibility criteria

Inclusion criteria

1. Informed consent is obtained;

2. newly diagnosed adenocarcinoma or squamous cell carcinoma stage IIIA, IIIB or IV or small cell lung cancer);

3. adults 18-80 years;

4. scheduled for chemotherapy as first part of the treatment:

Cisplatin/Gemcitabine (NSCLC) and Cisplatin/Etoposide (SCLC).

Exclusion criteria

1. Previous chemotherapy;

2. unable to evaluate response with the RECIST criteria;

3. unable to follow the instructions for the eNose measurement.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	N/A: single arm study

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	02-01-2009
Enrollment:	75
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	NL1536
NTR-old	NTR1607
Other	TPO : 589
ISRCTN	ISRCTN wordt niet meer aangevraagd

Study results

Summary results
N/A