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

Gepubliceerd: 29-12-2008 Laatst bijgewerkt: 18-08-2022

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.

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

Samenvatting

ID

NL-OMON27548

Bron
Nationaal Trial Register

Verkorte titel
SCENT (study 3)

Aandoening

electronic nose
smell-print
exhaled breath
lung cancer
chemotherapy

Ondersteuning

Primaire sponsor: MCL, Leeuwarden
Overige ondersteuning: MCL Leeuwarden

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

N/A

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Previous chemotherapy;

2. unable to evaluate response with the RECIST criteria;

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	02-01-2009
Aantal proefpersonen:	75
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	NL1536
NTR-old	NTR1607
Ander register	TPO : 589
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten

Samenvatting resultaten
N/A