eNose in Head and Neck Cancer.

No registrations found.

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

Summary

ID

NL-OMON21851

Source
Nationaal Trial Register

Brief title
SCENT 4

Health condition

head and neck cancer
oropharynx carcinoma

Sponsors and support

Primary sponsor: Medical Centre Leeuwarden
Source(s) of monetary or material Support: stichting longziekten Fryslan

Intervention

Outcome measures

Primary outcome

Breathprint of electronic nose.

Secondary outcome

N/A

Study description

Background summary

Rationale:

Head and neck cancer (HNC) is the fifth most common cancer worldwide and the most common neoplasm in central Asia and accounts about for 2 to 3% in U.S.A. mortality. HNC encompasses a variety of cancers, mostly (>90%) squamous cell cancers (HN SCCs), arising from a variety of sites from oral cavity, including lips, to larynx. The clinical presentation of HNC varies with the primary site. Patient delay especially holds true for the deeper regions like pharynx and larynx. In general dentists and general practitioners are the first to be consulted when symptoms occur and lack experience. In the ideal situation a rapid non invasive diagnostic test with high (especially negative) predictive value would be of great value if available for dentist and GP. Easy access to such a tool might lead to a diagnostic step in earlier phase of the disease with better prognosis and prevent medical overconsumption. The evolving field of exhaled breathmarkers might offer new opportunities in this respect.

Exhaled breath contains a complex mixture of several hundreds of volatile organic compounds (VOCs) . This could be established by gas chromatography and mass spectrometry (GC-MS). It has been shown that distinct biochemical markers have been found in the exhaled breath of patients with lung and breast cancer that could be discriminated from those of controls, suggesting that VOC analysis might be used as a non invasive marker of these cancers. After the introduction of electronic noses, the sampling of exhaled breath and its VOC-pattern (“breathprint”) has become readily available (“breatheomics”) based on pattern recognition without analyzing the individual molecular components, which potentially suffices for diagnostic objectives. The first studies by a sensor array in detecting lung cancer have demonstrated promising diagnostic accuracy showing that VOC patterns analysed by an electronic nose discriminated patients with Non Small Cell Lung Cancer from COPD patients as well as healthy controls. In our SCENT study 1 and 2 the diagnostic value of eNose already is being investigated in lung cancer and breast cancer.
In analogy with lung cancer there is evidence that HNCs can be discriminated by VOCs from a recent study with proton transfer reaction-mass spectrometry and maybe the electronic nose technique also applies to HNSCC and could be that rapid non invasive screening tool in HNSCC.
Therefore in the present study, we hypothesize that an electronic nose can discriminate the VOC pattern in exhaled breath between patients with Head and Neck Cancer from healthy controls. If confirmed, follow up of the breathprint after tumor resection is interesting.

Objective:

The primary objective of this study is: To examine the difference in VOC pattern of exhaled

air (breathprint) between patients with histology-confirmed diagnosis of head and neck squamous cell carcinoma (HNSCC) and healthy controls.

The secondary objectives are to investigate:

1. Whether the eNose can discriminate the breathprint of patients with HNSCC from patients with lung cancer and mamma carcinoma, included in SCENT study 1 and 2;

2. Whether the eNose can discriminate between the breathprints of patients with adenocarcinoma (NSCLC, mamma carcinoma) and squamous cell carcinoma (NSCLC, HNSCC);

3. Whether the eNose can discriminate between the breathprints of HNSCC patients before and after resection.

Study design:

Open observational, case control study. In addition a (short) longitudinal observational study in a subgroup.

Study population:

20 patients (18-80 yr) with histological confirmed head and neck squamous cell carcinoma (HNSCC) in oral and oropharyngeal region and 20 healthy controls, matched for sex, age and smoking status. The breathprints of patients with lung and breast carcinoma of SCENT 1 and 2 will also be used for investigation of the secondary study objectives.

Main study parameters/endpoints:

Primary outcome parameter is the difference in breathprints provided by the electronic nose.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

Patients and controls will visit the pulmonary function department one time. Participants refrain from eating, drinking and smoking 3 hours prior to the test. They first complete a questionnaire obtaining information about medical history , smoking status and actual medical condition and then proceed with an exhaled breath collection: exhaled vital capacity (VC) manoeuvre will be performed after breathing for 5 minutes through a mouthpiece. Then

spirometry will be done. These investigations are part of the routine pulmonary function testing and are safe procedures. Total investigation time will be less than 20 minutes. Patients whose therapy only consists of resection (earlier stages) will perform a second test 6 weeks post-resection. eNose testing might contribute to a simple non invasive diagnostic process in future in patients with HNC.

Study objective

we hypothesize that an electronic nose can discriminate the VOC pattern in exhaled breath between patients with Head and Neck Cancer from healthy controls.

Study design

Not applicable, all persons will be measured during diagnostic work-up.

Intervention

N/A

Contacts

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Eligibility criteria

Inclusion criteria

All patients (18-80 yr) with histologic confirmed oral and orofaryngeal squamous cell carcinoma.

Healthy controls, matched with the head and neck cancer for sex, age and smoking status.

Inclusion criteria:

1. Written informed consent obtained;

2. Head and neck cancer:

A. Adult 18-80 years;

B. Head and neck cancer of oral and oropharyngeal area;

C. Histology: squamous cell carcinoma.

3. Controls, matched for:

A. Age: <50 yr, 50=
B. Smoking status: Two groups:

i. Never, or ex-smoker > 3 months;

ii. Current smoker or ex-smoker < 3 months;

C. Sex.

Exclusion criteria

1. Periodontitis;

2. Consumption of alcohol in last 48 hours;

3. Any infection (especially of the airways) in the last 4 weeks;

4. Other known pulmonary disease;

5. Other or former malignancy;

6. Diabetes mellitus (documented in the past);

7. Pregnancy;

8. Untreated hypercholesterolaemia (documented in the past);

9. Significant cardiovascular disease (documented in the past).

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Suspended
Start date (anticipated):	01-04-2010
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	22-07-2010
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	NL2315
NTR-old	NTR2421
Other	TPO / CCMO : 678 / NL31491.099.10 ;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A