eNose in Colorectal Cancer.

No registrations found.

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

Summary

ID

NL-OMON24427

Source
NTR

Brief title
SCENT 5

Health condition

Colorectal Cancer

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

Breathprint of electronic nose.

Secondary outcome

N/A

Study description

Background summary

Rationale:

Colorectal cancer (CRC) is an important cancer in terms of incidence and mortality. There is evidence that screening of CRC improves prognosis and might eventually reduce incidence by detecting advanced adenomas and therefore population based screening procedures are currently under investigation. Screening tests for CRC can be grouped into 2 categories: a. tests that primarily detect cancer like tests based on fecal occult blood and b. tests that can detect cancer and advanced lesions, which include flexible sigmoidoscopy and colonoscopy. Other directions of making a diagnosis might be of importance since all tests have their shortcomings and no ideal screening procedure is available at the moment. The metabolic status of the patient could be of value in this respect. In a case control study colorectal cancer patients could be differentiated from healthy subjects with a sensitivity of 95 percent and specificity of 94 percent based on serum protein analysis. In another pilot study pre- and post operative groups of CRC could be discriminated based on serum metabolites with Gas chromatograph-mass spectrometry (GC-MS) in combination with pattern recognition techniques. So metabolic analysis, “metabolomics”, might be of value in diagnosis and monitoring in CRC in future.
During the last few years the analysis of exhaled breath has been proposed as a novel option for early detection of e.g. lung cancer. After the introduction of electronic noses, the sampling of exhaled breath and its VOC-pattern 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. Currently we are investigating the value of the eNose in lung cancer, breast cancer and head and neck squamous cell carcinoma (HNSCC) in our other SCENT studies that will give more insight into the value of electronic nose technology in each of these cancers. One of the postulated mechanisms for a change in breathprint is a change in the metabolic status induced by the cancer and it would be interesting to investigate whether resection of the tumour also changes the breathprint determined by the electronic nose.

In conclusion good screening procedures are important in CRC, but existing tests do have their shortcomings and maybe the electronic nose technique could be that rapid non invasive screening tool in colorectal carcinoma that we need. Therefore in the present study, we hypothesize that an electronic nose can discriminate the VOC pattern in exhaled breath between patients with colorectal cancer and healthy controls. If confirmed, follow up of the breathprint after tumour 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 colorectal cancer and healthy controls.

The secondary objectives are to investigate:

1. Whether the eNose can discriminate the breathprint of patients with CRC from patients with lung cancer, Head Neck Squamous Cell Carcinoma (HNSCC) and mamma carcinoma, all groups included in SCENT study 1,2 and 4;

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

3. Whether the eNose can discriminate between the breathprints of patients before and 6 weeks after resection of the CRC that is localized proximal to the rectum.

Study design:

Open observational, case control study. In addition for the group CRC proximal to the rectum a (short) longitudinal observational study.

Study population:

20 patients (18-80 yr) with histological confirmed CRC and 20 healthy controls, matched for sex, age and smoking status, who had normal findings at colonoscopy performed for various reasons. The breathprints of patients with lung, breast carcinoma and Head and Neck squamous cell carcinoma(HNSCC) of SCENT 1,2 and 4 will also be used for investigation of the secondary study objectives.

Main study parameters/endpoints:

Primary outcome parameter is the breathprint 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 with CRC proximal to the rectum will perform a second test 6 weeks post-resection (and before any adjuvant therapy in case of advanced disease is started).
eNose testing might contribute to a simple non invasive diagnostic and monitoring process in future in patients with CRC.

Study objective

we hypothesize that an electronic nose can discriminate the VOC pattern in exhaled breath between patients with colorectal cancer and healthy controls.

Study design

Not applicable: All measured before therapy is started. Only second measurement 6 weeks post operative in subgroup that will have no treatment besides surgery.

Intervention

N/A

Contacts

Public
Dept. of pulmonary diseases
MCL
Leeuwarden

J. Maten, van der
Leeuwarden
The Netherlands
+31 (0)58 286 6190
Scientific
Dept. of pulmonary diseases
MCL
Leeuwarden

J. Maten, van der
Leeuwarden
The Netherlands
+31 (0)58 286 6190

Eligibility criteria

Inclusion criteria

All patients (18-80 yr) with histological confirmed CRC (20 patients) will be included in the analysis of the present study;

20 healthy controls, matched with the CRC patients for sex, age and smoking status, who had normal findings at colonoscopy performed for various reasons.

Inclusion criteria:

1. Written informed consent obtained;

2. Colorectal cancer:
A. Adult 18-80 years;

B. Histological proven CRC.

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;

D. Normal findings at colonoscopy performed for various reasons like e.g. irritable bowel syndrome and familial adenomatous polyposis.

Exclusion criteria

1. Periodontitis;

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

3. Known pulmonary disease;

4. Other or former malignancy;

5. Diabetes mellitus (documented in the past);

6. Pregnancy;

7. Untreated hypercholesterolaemia (documented in the past);

8. Significant cardiovascular disease (documented in the past);

9. Healthy controls: Any abnormal findings at colonoscopy (e.g. like polyps).

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):	01-07-2010
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	NL2317
NTR-old	NTR2423
Other	TPO / CCMO : 697 / NL32538.099.10 ;
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A