Smellprints in lung Cancer; the role of ENose in diagnosis and Treatment (SCENT)
part 5: Diagnostic value of the eNose in Colorectal Cancer

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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:...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Observational non invasive

Summary

ID

NL-OMON34063

Source
ToetsingOnline

Brief title
eNose in colorectal cancer/SCENT study, part 5

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
bowel cancer, colorectal carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Leeuwarden
Source(s) of monetary or material Support: Stichting Longgeneeskunde Fryslan

Intervention

Keyword: Colorectal carcinoma, electronic nose, exhaled breath, Smellprints

Outcome measures

Primary outcome

primary outcome parameter is the difference in breathprints provided by the

electronic nose

Secondary outcome

not applicable

Study description

Background summary

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 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 and 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.

Study 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:
a. 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.
b. Whether the eNose can discriminate between the breathprints of patients with adenocarcinoma (NSCLC, mamma carcinoma, CRC) and squamous cell carcinoma (NSCLC, HNSCC).
c. 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.

Patient recruitment is based on histologic diagnosis of CRC.

At the Pulmonary function department each participant will follow this sequence:
1. questionnaire
2. exhaled breath collection

3. pulmonary function test: spirometry

Study burden and risks

Patients and controls will visit the pulmonary function department.
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. eNose testing might contribute to a simple
non invasive diagnostic process in future
in patients with CRC.

Patients with CRC with tumour proximal to the rectum shall have a second test 6
weeks post resection (before adjuvant treatment if necessary)

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

Written informed consent obtained.
Colorectal cancer:
• adult 18-80 years
• histological proven CRC
Controls:
Matched for:
• Age: <50 yr, 50>=age=<70, 70• smoking status: two groups
A. never, or ex-smoker > 3 months
B. current smoker or ex-smoker < 3 months.
• sex
• Normal findings at colonoscopy performed for various reasons like e.g. irritable bowel syndrome and familial adenomatous polyposis.

Exclusion criteria

• periodontitis
• any infection (especially of the airways) in the last 4 weeks
• known pulmonary disease
• Other or former malignancy
• Diabetes mellitus (documented in the past)
• Pregnancy
• Untreated hypercholesterolaemia (documented in the past)
• Significant cardiovascular disease (documented in the past)
• Healthy controls: Any abnormal findings at colonoscopy (e.g. like polyps)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other

Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-08-2010
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO

Date:	01-07-2010
Application type:	First submission
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	NL32538.099.10
Other	TC 1604 (Nederlands trial register)