Electronic nose for breath analysis after curative Surgery to detect distant metastases or locoregional recurrence of colon cancer

No registrations found.

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

Summary

ID

NL-OMON22434

Source
Nationaal Trial Register

Brief title
EASIER study

Health condition

Patients undergoing curative treatment for CRC

Sponsors and support

Primary sponsor: • The ‘Medisch Specialistisch Bedrijf’(MSB) of Isala has invested in The eNose Company, Zutphen, The Netherlands. The researchers have received a grant from the Innovation & Science fund Isala. • The eNose Company invests by making the eNose devices, disposable mouthpieces and analysis of the breath tests available.
Source(s) of monetary or material Support: Innovation & Science fund Isala
The eNose company received an OP-Oost grant. The introduction of eNose in Isala is supported by this grant

Intervention

Outcome measures

Primary outcome

the diagnostic accuracy of eNose in the detection of recurrent CRC

Secondary outcome

none

Study description

Background summary

Rationale
Colorectal carcinoma (CRC) has a high incidence worldwide and in the Netherlands. After curative treatment, there is a risk of recurrence of 15%. Early detection of an asymptomatic recurrence can still lead to curative treatment. The current follow-up studies do not have optimal sensitivity and specificity.
Multiple studies have demonstrated that volatile organic compound (VOC) analysis has a high diagnostic accuracy for CRC. Furthermore, a pilot study has recently shown that there is a distinctive character in VOC in patients after curative resection of CRC with and without recurrence.

Objective
In this study it is investigated whether eNose is able to distinguish patients with recurrent CRC after curative resection from patients without recurrent CRC based on VOC patterns. The primary outcome measure is the diagnostic accuracy of eNose in the detection of recurrent CRC

Study design
This study concerns a prospective validation study as a follow-up to the pilot study that was carried out

Study population
All patients with AJCC stage I-IV CRC after a R0 resection, and are offered follow-up according to Dutch guidelines are asked to participate. Patients with stage IV (synchronous or metachronous metastases) who have been treated with curative intention are included. Patients with a local resection and a pT1N0Mx are excluded.
Intervention
Patients are given a breath test during the first three years of follow-up when they come for a regular follow-up with imaging. If verification of only CEA determination (year 4 and 5) gives rise to imaging tests, they will be asked for an extra breath test.

Main study endpoint
We want to demonstrate a sensitivity of at least 70% using the eNose to detect recurrent CRC.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness
Patients do not directly benefit from participating in this study. The outcome of the breath test is not shared with patients and practitioners and has no treatment consequences. Nevertheless, participation in this study is not associated with any health risk and the burden to the patient is a 5 minute breath test at a time when the patient enters the hospital for standard follow-up examinations.

Study objective

eNose is able to detect metastases of CRC with a sensitivity of at least 70%

Study design

The primary outcome measure is the diagnostic accuracy of eNose in the detection of recurrent CRC. The sensitivity, specificity, positive predictive value, negative predictive value, accuracy are calculated after the achieved numbers of patients are included. This is expected on 01-03-2023

Intervention

Patients are given a breath test during the first three years of follow-up if they come for a regular follow-up with imaging. If verification of only CEA determination (year 4 and 5) gives rise to imaging tests, they will be asked for an extra breath test

Contacts

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Eligibility criteria

Inclusion criteria

1. Follow-up patients with an intentional curative treatment of CRC stage I to IV
• a CRC treated with curative intent by means of a colorectal resection
• curative treatment of synchronous metastases in combination with colorectal resection
• curatively treated metachronous metastases, after colorectal resection
2. Age ≥ 18 years.

Exclusion criteria

1. Not proficient in Dutch
2. Reason to believe that the patient cannot perform a breath test
3. CRC not treated curatively
4. CRC pT1N0Mx / pT1NxMx (patients receiving endoscopic control only)
5. Local (surgical or endoscopic) resection
6. Active treatment of other malignancies within the past three months

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2020
Enrollment:	1184
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	23-11-2020
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	NL9084
Other	METC isala : METC Isala191103

Study results

Summary results

Steenhuis, E.G.M., Schoenaker, I.J.H., de Groot, J.W.B., Fiebrich, H.B., de Graaf, J.C., Brohet, R.M., van Dijk, J.D., van Westreenen, H.L., Siersema, P.D., de Vos tot Nederveen Cappel, W.H. (2020). Feasibility of volatile organic compound in breath analysis in the follow-up of colorectal cancer: A pilot study. European Journal of Surgical Oncology, 46(11), 2068-2073