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

Gepubliceerd: 23-11-2020 Laatst bijgewerkt: 18-08-2022

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

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

Samenvatting

ID

NL-OMON22434

Bron
Nationaal Trial Register

Verkorte titel
EASIER study

Aandoening

Patients undergoing curative treatment for CRC

Ondersteuning

Primaire 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.
Overige ondersteuning: Innovation & Science fund Isala
The eNose company received an OP-Oost grant. The introduction of eNose in Isala is supported by this grant

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

the diagnostic accuracy of eNose in the detection of recurrent CRC

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-03-2020
Aantal proefpersonen:	1184

Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	23-11-2020
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	NL9084
Ander register	METC isala : METC Isala191103

Resultaten

Samenvatting resultaten

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