Detection of dysplastic and neoplastic lesions in patients with Barrett’s esophagus through exhaled breath using an electronic nose device (eNose)

Gepubliceerd: 26-02-2018 Laatst bijgewerkt: 18-08-2022

The eNose is able to differentiate between BE patients with dysplastic or neoplastic lesions and patients with NDBE

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

Samenvatting

ID

NL-OMON24189

Bron
Nationaal Trial Register

Verkorte titel
enose surveillance

Aandoening

Barrett's esophagus, dysplasia, esophageal adenocarcinoma

Ondersteuning

Primaire sponsor: Radboud university medical center
Overige ondersteuning: fund = initiator = sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The ability to differentiate between BE patients with dysplastic or neoplastic lesions and patients with NDBE by eNose in terms of sensitivity, specificity and accuracy.

Toelichting onderzoek

Achtergrond van het onderzoek

Summary

Rationale:

To detect dysplastic or early neoplastic lesions, endoscopic surveillance is recommended in patients with Barrett's esophagus (BE). The number of patients experiencing discomfort of upper endoscopy is much larger than the number of patients that experience potential benefit of the procedure, as only a few will develop malignancy. Currently, a less burdensome, highly accurate surveillance method for BE is lacking. The aim of the study is to establish the accuracy with which the eNose can differentiate BE patients with dysplasia from BE patients without dysplasia.

Main objectives

- To assess whether it is possible to detect dysplastic or neoplastic lesions in patients with Barrett's esophagus noninvasively by VOC breath recognition using an electronic nose device.

- To assess the acceptance rate of using the eNose device.

Study design:

The current study will be a multi-center cross-sectional, exploratory proof of principle study to explore whether an electronic nose device is able to distinguish BE patients with dysplasia from those without dysplasia by VOC analysis of patient breath samples.

Study population:

The study population consist of adult patients who are undergoing a clinically indicated surveillance upper endoscopy. Patients who are planned to undergo endoscopy will be asked to participate in this study. Subjects will be divided into two groups based on current diagnosis: (1) patients with known BE without dysplasia (n=25), (2) patients with BE and LGD (n=25), (3) and patients with BE and HGD or EAC (n=25).

Main study parameters / endpoints:

1. The ability to distinguish between BE patients with dysplastic or neoplastic lesions and

patients with NDBE by eNose in terms of sensitivity, specificity and accuracy.

2. Cross-validated accuracy with which the eNose can differentiate between BE patients with dysplastic or neoplastic lesions and patients with NDBE, defined as the percentage of correctly classified patients using the leave-some out method.

3. Acceptance rate of using the eNose

Doel van het onderzoek

The eNose is able to differentiate between BE patients with dysplastic or neoplastic lesions and patients with NDBE

Onderzoeksopzet

Each patient will be recruited for breath testing immediately before regular upper endoscopy and will provide a 5-minute continuous breath sample.

Onderzoeksproduct en/of interventie

Device: Aeonose

An electronic nose device is an artificial olfactory system that analyses volatile organic compounds (VOCs) in exhaled breath. The AeonoseTM is a handheld device of 650 gram. A nose clip will be used to prevent the entry of non-filtered air and patients will be instructed to enclose the mouthpiece with their mouth at all times. A measurement cycle lasts for about 15 minutes, of which 5 minutes of in-and exhalation by the patient takes place.

Contactpersonen

Publiek

Department of Gastroenterology and Hepatology (455)

Yonne Peters
P.O. box 9101

Nijmegen 6500 HB
The Netherlands
+31615956464

Wetenschappelijk

Department of Gastroenterology and Hepatology (455)

Yonne Peters
P.O. box 9101

Nijmegen 6500 HB
The Netherlands
+31615956464

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Subjects, who are/have:

- Aged 18 years or older.

- Able to give signed informed consent.

- Diagnosed with a BE segment >1cm in maximal extent endoscopically (C1Mx)

- Histology showing evidence of intestinal metaplasia

1. Patients with known BE without dysplasia, who are/have:

- Histology showing no evidence of dysplasia.

- Undergoing clinically indicated surveillance endoscopy.

2. Patients with known BE, with a diagnosis of LGD, who are/have:

- Histology showing evidence of low grade dysplasia.

- Undergoing clinically indicated diagnostic endoscopy or had an endoscopy in the last 3 months.

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3. Patients with known BE, with a diagnosis of HGD or EAC, who are/have:

- Histology showing evidence of high grade dysplasia or esophageal adenocarcinoma.

- Undergoing clinically indicated diagnostic or therapeutic endoscopy or had an endoscopy showing HGD/EAC in the last 3 months.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Patients with a history of any type of malignancy except for esophageal adenocarcinoma and non-melanoma skin cancer.

- Patients with prior history of ablation (photodynamic therapy, radiofrequency ablation, cryotherapy, argon plasma coagulation) or endoscopic mucosal resection.

- Patient with current history of eosinophilic esophagitis, infectious esophagitis, achalasia, esophagitis according to the Los Angeles classification (gr. A-D) or uninvestigated dysphagia.

- Patients with history of known varices or cirrhosis.

- Patients with history of esophageal or gastric resection or surgery which has changed the esophageal anatomy.

- Patients with a history of esophageal squamous dysplasia.

- Antibiotic use within the last 2 months before eNose procedure.

- Infection of the oral cavity.

- Patients with H. Pylori infection.

- Patients who are unable to perform breathing manouevre needed for eNose-analysis of exhaled air.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd

Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Anders
(Verwachte) startdatum:	01-03-2018
Aantal proefpersonen:	75
Type:	Onbekend

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	26-02-2018
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	NL6870
NTR-old	NTR7048
Ander register	CMO radboudumc : 2017-3543

Resultaten