Screening for Barrett’s esophagus: accuracy of exhaled breath analysis using an electronic nose device

Gepubliceerd: 11-10-2019 Laatst bijgewerkt: 13-12-2022

the Aeonose is able to discriminate between patients with Barrett’s esophagus versus patients without a diagnosis of Barrett’s esophagus.

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

Samenvatting

ID

NL-OMON21425

Bron
NTR

Verkorte titel
eNose Barrett

Aandoening

Barrett's esophagus

Ondersteuning

Primaire sponsor: Radboudumc
Overige ondersteuning: The Aeonose™ devices are provided by the eNose Company (Zutphen, the Netherlands) for use in research. No additional funding for this study was provided by industry and all research was investigator initiated.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Sensitivity and specificity of the eNose for detecting BE with the diagnosis made by upper endoscopy as the reference standard.

Toelichting onderzoek

Achtergrond van het onderzoek

Primary objective: To determine the diagnostic accuracy of exhaled breath analysis with the Aeonose to discriminate between patients with Barrett’s esophagus versus patients without a diagnosis of Barrett’s esophagus.
Study design: The present multicenter case-control study will include 980 patients who are undergoing a clinically indicated (surveillance) upper endoscopy. First a database of breath prints will be developed to detect BE. In this study phase the Aeonose™ will be trained and the database of breath prints will be verified using “leave 10% out” cross validation. After the calibration phase the diagnostic accuracy of Aeonose™ will be assessed in new study patients (external validation).
Study population: Patients who are planned to undergo a endoscopy will be asked to participate in this study. Subjects will be divided into 3 groups based on current diagnosis: (1) patients with known BE, (2) patients with reflux symptoms and (3) healthy individuals without reflux symptoms.
Main study parameters/ endpoints: The primary outcome of the study is sensitivity and specificity of the eNose for detecting BE with the diagnosis made by upper endoscopy as the reference standard. Secondary study endpoints are acceptance rates for breath testing, technical or patient related problems obtaining a read-out from the Aeonose™, accuracy of the eNose with which it could distinguish patients with BE from patients with GERD, reproducibility by repeated testing, effect of PPI use on the accuracy of the eNose for detecting BE.

Doel van het onderzoek

the Aeonose is able to discriminate between patients with Barrett’s esophagus versus patients without a diagnosis of Barrett’s esophagus.

Onderzoeksopzet

NA

Contactpersonen

Publiek

Radboudumc
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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Aged 18 years or older
- Undergoing a clinically indicated (surveillance) endoscopy
- Able to give signed informed consent
1. Patients with known BE (defined as ≥1 cm of columnar mucosa with histopathologic confirmation of intestinal metaplasia without dysplasia)
2. Individuals with GERD symptoms without BE (GERDQ-score ≥8 or the endoscopic presence of reflux esophagitis)
3. ‘Healthy’ controls without BE or GERD

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Patients with a history of any type of malignancy (not including basal-cell skin cancer (BCC) and squamous-cell skin cancer (SCC))
- Prior surgical esophageal or gastric resection or prior ablative therapy
- Patients who are unable to perform breathing maneuver needed for Aeonose-analysis of exhaled breath

Withdrawal criteria after initial study inclusion:
Patients can be withdrawn from the study if:
- Incomplete upper endoscopy
- Active H. Pylori infection
- BE segment <1cm or no intestinal metaplasia in the esophagus

- Intestinal metaplasia in the stomach

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:	Werving gestart
(Verwachte) startdatum:	14-10-2019
Aantal proefpersonen:	980
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	11-10-2019
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	NL8083
Ander register	CMO regio Arnhem-Nijmegen / Lokale CMO Radboudumc : 2019-5677

Resultaten