

Detection of Barrett's esophagus through exhaled breath using an electronic nose device (AeoNose™)

No registrations found.

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

Summary

ID

NL-OMON26864

Source

Nationaal Trial Register

Brief title

eNose

Health condition

Gastroesophageal reflux disease (GERD)

Barrett's Esophagus (BE)

Esophageal Adenocarcinoma (EAC)

Sponsors and support

Primary sponsor: Radboud University Medical Center

Source(s) of monetary or material Support: fund = initiator = sponsor

Intervention

Outcome measures

Primary outcome

The ability to distinguish between patients with BE, healthy individuals, and patients with

reflux symptoms by eNose in terms of sensitivity, specificity and accuracy.

Secondary outcome

Cross-validated accuracy with which the eNose can distinguish between patients with BE, healthy individuals and patients with reflux symptoms, defined as the percentage of correctly classified patients using the leave-some out method.

- Acceptance rate of using the eNose

Study description

Background summary

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

Study objective

The enose is able to detect BE through exhaled breath.

Study design

time frame: 1 year

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

Subjects, who are:

- Aged 18 years or older.
- Able to give signed informed consent.

1. Patients with known Barrett's Esophagus (BE), who are.

- Diagnosed with a BE segment >1cm in maximal extent endoscopically (CxM1).
- Histology showing evidence of intestinal metaplasia without presence of dysplasia.
- Undergoing clinically indicated (surveillance) endoscopy.

2. Individuals with reflux symptoms without BE, who are.

- Undergoing clinically indicated diagnostic endoscopy due to upper gastrointestinal symptoms (non-acute symptoms of heartburn, pain in the epigastric region or bloating, with the cause likely to be located in the upper gastrointestinal tract).

- GerdQ self-assessment questionnaire score ≥ 8 .

3. Healthy individuals without BE and without reflux symptoms, who are

- Undergoing clinically indicated diagnostic endoscopy.

- GerdQ self-assessment questionnaire score < 6 .

Exclusion criteria

- Patients with a history of any type of malignancy (not including basal-cell skin cancer (BCC) and squamous-cell skin cancer (SCC))

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

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

- Patients who are unable to perform breathing maneuver needed for Aeonose-analysis of exhaled air

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	01-01-2018
Enrollment:	375

Type: Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date: 28-12-2017

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	NL6750
NTR-old	NTR6928
Other	CMO Radboudumc : 2017-3505

Study results