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

No registrations found.

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

## Summary

### ID

NL-OMON21425

**Source**
NTR

**Brief title**
eNose Barrett

**Health condition**

Barrett's esophagus

### Sponsors and support

**Primary sponsor:** Radboudumc
**Source(s) of monetary or material Support:** 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.

### Intervention

### Outcome measures

**Primary outcome**

Sensitivity and specificity of the eNose for detecting BE with the diagnosis made by upper

endoscopy as the reference standard.

### Secondary outcome

- Acceptance rates for breath testing
- Patient acceptability of the eNose procedure
- 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

## Study description

### Background summary

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.

### Study objective

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

### Study design

NA

# Contacts

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# Eligibility criteria

## Inclusion criteria

- 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

## Exclusion criteria

- 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

# 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): | 14-10-2019 |
| Enrollment: | 980 |
| Type: | Anticipated |

## IPD sharing statement

**Plan to share IPD:** Undecided

# Ethics review

Positive opinion

| | |
|---|---|
| Date: | 11-10-2019 |
| 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 | NL8083 |
| Other | CMO regio Arnhem-Nijmegen / Lokale CMO Radboudumc : 2019-5677 |

# Study results