# Trans-Oral Sampling as an alternative for Barrett Surveillance: Transitioning Across Different Sampling Modalities through Cross-Validation; .

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To evaluate the consistency and diagnostic accuracy of risk profiles using genetic markers across three different sampling modalities: biopsy, brush sampling, and TOS.

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| **Ethical review** | Approved WMO |
| **Status** | Pending |
| **Health condition type** | Benign neoplasms gastrointestinal |
| **Study type** | Observational invasive |

## Summary

### ID

NL-OMON57125

**Source**
ToetsingOnline

**Brief title**
The TOSS Transition study

### Condition

- Benign neoplasms gastrointestinal

**Synonym**
Barrett Esophagus, Dysplasia

**Research involving**
Human

### Sponsors and support

**Primary sponsor:** Amsterdam UMC
**Source(s) of monetary or material Support:** onderzoeksgroepgelden verzameld door

onderzoeksgroep: Esopheal Research Team

## Intervention

**Keyword:** Barrett Esophagus, minimal invasive sampling, Risk stratification, Surveillance

## Outcome measures

### Primary outcome

To compare the diagnostic accuracy (sensitivity and specificity) of genetic markers in detecting at-risk patients (defined as having a diagnosis of LGD, HGD, or EAC) across three sampling modalities: biopsy, brush sampling, and TOS*

### Secondary outcome

2 To compare the diagnostic accuracy (sensitivity and specificity) of genetic markers in detecting high-risk patients (defined as having a diagnosis HGD or EAC) across three sampling modalities: biopsy, brush sampling, and TOS

3 The number and type of genetic markers uniquely detected by each sampling method and their relative abundance or detection rate in each method.

4. The spatial distribution patterns and detection rates of progression-associated genetic markers in biopsy, brush sampling, and TOS samples.

# Study description

### Background summary

: In Western countries, there is a notable increase in the incidence of esophageal cancer and Barrett's Esophagus (BE). This rising trend underscores the urgent need for effective surveillance strategies. As advanced screening technologies become more accessible, a significant number of patients are being enrolled in surveillance programs. Surveillance is critical, as esophageal adenocarcinoma (EAC) often has a poor prognosis if diagnosed at an advanced

stage. Early detection through surveillance facilitates timely endoscopic interventions, significantly reducing mortality and morbidity.

Current endoscopic surveillance methods for BE patients face several challenges. They are expensive, impose a significant burden on patients, and are generally not cost-effective. Traditional biopsy-based pathology assessments, the cornerstone of this strategy, suffer from subjectivity, with poor inter-pathologist agreement and limited predictive value for assessing progression risks. Additionally, the focal nature of neoplasia in the esophagus means that biopsies can miss localized lesions due to their limited sampling scope.

It is suggested that employing broad-area sampling with a brushing technique as a supplemental method potentially enhances the detection rates of neoplastic changes in BE. However both brushing and traditional methods still necessitate costly invasive endoscopic procedures. As an innovative step forward, the transoral sampling (TOS) 'pill-on-a-string' device is designed to sample the entire circumference of the esophagus non-invasively. This method could significantly shift current surveillance paradigms by providing comprehensive and patient-friendly approaches, although it still lacks adequate risk stratification tools.

Recent developments in genetic profiling have introduced promising tools for enhancing BE surveillance. Genetic markers has revealed specific patterns that may be pivotal in predicting the progression from Non Dysplastic Barrett's Esophagus (NDBE) to esophageal adenocarcinoma. These markers hold potential not only for improving diagnostic accuracy but also for stratifying patients according to their risk levels. By employing a comprehensive genetic panel, surveillance methods could shift from invasive procedures to more patient-friendly approaches.

This study aims to validate these genetic markers across different sampling modalities, focusing on their ability to consistently stratify risk and detect early neoplastic changes, and to integrate them into an optimal panel for use with the 'pill-on-a-string' TOS device. By assessing these markers across different sampling modalities, this research seeks to demonstrate their potential in streamlining BE surveillance, reducing invasiveness, and enhancing cost-effectiveness.

**Study objective**

To evaluate the consistency and diagnostic accuracy of risk profiles using genetic markers across three different sampling modalities: biopsy, brush sampling, and TOS.

**Study design**

This is a multicenter, prospective cohort observational study.

**Study burden and risks**

In this study, patients with Barrett's esophagus undergo standard endoscopic evaluations, supplemented with additional tissue sampling methods such as the "pill-on-a-string" (PoS) and brush sampling. These extra procedures add minimal burden since they are performed during already scheduled endoscopies. For some patients, an additional visit is required for a second PoS sampling. The risks associated with these procedures are low; the most common side effect is a temporary sore throat. In rare instances, the PoS pill may detach, but this can be easily managed with a follow-up endoscopy. Overall, the extra burden and risks for participants are negligible.

# Contacts

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# Trial sites

## Listed location countries

Netherlands

# Eligibility criteria

**Age**
Adults (18-64 years)
Elderly (65 years and older)

## Inclusion criteria

- Patients age: >= 18 years
- BE with a maximal extent of >=1cm
- Willingness to undergo an esophagogastroduodenoscopy (EGD) with sampling using a pill-on-a-string device.
- Willingness to undergo an trans oral sampling procedure with a pill on the string device
- Cohort 1: Barrett's Esophagus (BE) patients who, within 18 months before or during the baseline endoscopy, have the worst grade pathology diagnosis of High-Grade Dysplasia (HGD) or Esophageal Adenocarcinoma (EAC), or present a visible lesion suspected of neoplasia.
- Cohort 2: Barrett's Esophagus (BE) patients who, within 18 months before or during the baseline endoscopy, have the worst grade pathology diagnosis of Low-Grade Dysplasia (LGD).
- Cohort 3: Barrett's Esophagus (BE) patients who, within 18 months before or during the baseline endoscopy, show no evidence of dysplasia
- Ability to give written, informed consent and understand the responsibilities of participation

## Exclusion criteria

• Patients within eight weeks after endoscopy with biopsies and/or ER
• History of esophageal or gastric surgery other than fundoplication
• History of endoscopic treatment for neoplasia in the esophagus or stomach.
• History of esophageal ablation or dilation therapy
• Presence of esophageal varices and/or suspected portal hypertension during imaging endoscopy at baseline
• Present Dysphagia/ swallowing disorders at the time of screening and participation
• Pregnancy
• Patients with known or suspected anatomical abnormalities of the esophagus or stomach
• Patients taking anti-thrombotic drugs that cannot be temporarily discontinued
• Subject has a known history of unresolved drug or alcohol dependency that would limit ability to comprehend or follow instructions related to informed consent, post-treatment instructions, or follow-up guidelines

# Study design

### Design

**Study type:** Observational invasive

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| Masking: | Open (masking not used) |
| Control: | Uncontrolled |
| Primary purpose: | Diagnostic |

### Recruitment

NL

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|---|---|
| Recruitment status: | Pending |
| Start date (anticipated): | 10-11-2024 |
| Enrollment: | 230 |
| Type: | Anticipated |

## Ethics review

Approved WMO

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| Date: | 21-11-2024 |
| Application type: | First submission |
| Review commission: | METC Amsterdam UMC |

## 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 |
|---|---|
| CCMO | NL87263.018.24 |