Trans-Oral Sampling as an alternative Surveillance of Barrett*s Esophagus Pilot:
The TOSS pilot-study

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to determine the number of sufficient quality samples obtained through the use of the Cytosponge, which could potentially serve as a substitute for endoscopic sampling.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Benign neoplasms gastrointestinal
Study type	Observational invasive

Summary

ID

NL-OMON56023

Source
ToetsingOnline

Brief title
TOSS pilot study

Condition

- Benign neoplasms gastrointestinal

Synonym
Barrett Esophagus, dysplasia

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Barrett Esophagus, Sampling, Surveillance strategy, Trans-Oral

Outcome measures

Primary outcome

The amount of samples collected with the Cytosponge that contain columnar cells

and are processed to clot preparations that are at least 5mm in size.

Secondary outcome

The number of successful Cytosponge study procedures.

The concordance between the pathology review of endoscopic samples and

samples collected with the Cytosponge

The concordance between 2 samples of the same subject taken with the Cytosponge

Study description

Background summary

In the western world, there is an alarming increase in incidence of esophageal cancer and Barrett's esophagus (BE). As the incidence is increasing and better screening tools become available, a large group of patients with BE will be enrolled in BE surveillance programs.

Esophageal adenocarcinoma (EAC) has a poor prognosis when diagnosed at an advanced stage. Therefore, an adequate surveillance strategy is necessary as it enables early detection and identification of EAC, allowing endoscopic treatment with lower mortality and morbidity.

However, endoscopic surveillance of BE patients with a low risk of progression is expensive, burdensome for the patient and time consuming. Still these regular surveillance endoscopies are required because there is no proper substitute. In order to unburden these low risk patients and ensure adequate utilization of health care resources, there is a need for a reliable alternative surveillance strategy.

The Cytosponge is a Trans Oral Sampling (TOS) device that can be easily administered. The TOS device was previously mainly investigated in the setting of screening for the presence of BE, but the potential for surveillance of known BE patients remains unclear. With good quality sampling using the Cytosponge, trans oral sampling could be a better alternative to endoscopic surveillance of Barrett*s Esophagus.

Study objective

to determine the number of sufficient quality samples obtained through the use of the Cytosponge, which could potentially serve as a substitute for endoscopic sampling.

Study design

This is a single centre, prospective pilot study on the feasibility of trans oral sampling for surveillance of Barretts esophagus patients.

Study burden and risks

burden and risk are minimal; however, only the additional hospital visits for patients in cohort 2 can be considered burdensome

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Patients age: >= 18 years
- BE with a maximal extent of >=4cm
- Cohort 1: Patients referred for endoscopic treatment of HGD or EAC
- Cohort 2: Patients with known BE without a diagnosis of HGD or EAC in the previous 18 months, undergoing endoscopic surveillance
- 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 Nissen fundoplication
• History of esophageal ablation or dilation therapy
• Presence of esophageal varices and/or suspected portal hypertension
• pregnancy
• present Dysphagia/ swallowing disorders at the time of screening and participation
• 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

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	20-10-2023
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	14-08-2023
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	NL84099.018.23