Ultralong-segment Barrett*s esophagus: towards a capsule-sponge surveillance strategy (ULSBE-Endosign study).

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Ethical review	Approved WMO
Status	Pending
Health condition type	Malignant and unspecified neoplasms gastrointestinal NEC
Study type	Interventional

Summary

ID

NL-OMON57287

Source
ToetsingOnline

Brief title
ULSBE-Endosign study

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC
- Gastrointestinal neoplasms malignant and unspecified

Synonym
Barrett's esophagus

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,Cyted Health

Intervention

Keyword: Barrett's esophagus, Capsule sponge test, Endosign, Surveillance

Outcome measures

Primary outcome

The primary aim of this study is to investigate the concordance of the Endosign test to predict any grade of dysplasia or EAC in ULSBE patients compared to surveillance endoscopy by a BE expert.

Secondary outcome

Secondary objectives are:

• To determine the acceptability of the Endosign test in a ULSBE surveillance cohort

• To determine the sensitivity and specificity of the capsule-sponge to detect any form of dysplasia or EAC in a cohort of ULSBE patients

• To determine the additional value of p53 IHC in risk stratifying patients with ULSBE

• To develop a risk stratification model for ULSBE patients using clinical risk factors and p53 IHC

• To investigate whether a newly developed sWGS panel could improve the diagnostic accuracy of the capsule-sponge test

• To validate the sensitivity of the current sequencing approach using methylation and instability to detect neoplastic progression, and investigate it*s prognostic sensitivity in NDBE patients.

Study description

Background summary

Barrett*s esophagus (BE) surveillance using conventional esophagogastroduodenoscopy (EGD) aims to detect dysplasia and esophageal adenocarcinoma (EAC) at an early, treatable stage. However, given the relatively low progression rates of BE, the number of EGDs required is a burden to patients and society. The capsule-sponge Endosign test is a non-invasive test which might be able to replace EGD. Developed for BE screening, recent work has shown it might also be suitable to detect dysplasia in BE patients under surveillance. Patients at presumed high risk of neoplastic progression are patients with an ultralong-segment (>10cm) Barrett*s esophagus (ULSBE).

Study objective

The primary objective is to investigate the concordance between the Endosign test and EGD by an expert endoscopist for detecting dysplasia and/or EAC in a high-risk category of ULSBE patients. Secondary objectives are to determine the acceptability and sensitivity and specificity of the Endosign test in a ULSBE surveillance cohort, to develop a clinical and p53 risk stratification model to identify a high-risk ULSBE group and to investigate if novel sequencing-based panels on the Endosign test could increase its diagnostic accuracy.

Study design

In this clinical trial we will recruit two cohorts, the first cohort consists of patients who have dysplasia and/or early stage EAC who require treatment. The second cohort consists of ULSBE patients under surveillance. Both groups will swallow the Endosign test prior to their endoscopy. Patients who are treated will swallow the Endosign test once. The surveillance cohort will be a longitudinal cohort, in which the participants are asked to swallow the Endosign test a second time at their next surveillance endoscopy. The study will run for 3 years. Additionally, we will use p53 immunohistochemistry (IHC) to investigate its potential to risk stratify ULSBE patients, and we will test a novel biomarkers including a sWGS panel on the capsule-sponge test.

Intervention

The participants will be asked to swallow the Endosign test prior to their standard-of-care endoscopy on the same day. The capsule-sponge test is a pill on a string which the patient swallows under guidance of a dedicated nurse or doctor. Once the pill reaches the stomach, it dissolves and a mesh unfolds within approximately 7 minutes. After this period the nurse or doctor will pull back the sponge, and on the way out the sponge scrapes cells from the esophagus

which can be analyzed in the laboratory. Using p53 and morphological features the sponge is able to identify high-risk features corresponding with dysplasia.

Study burden and risks

Patients will undergo the Endosign test prior to their endoscopy. This test is usually tolerated well, and has been extensively tested in prior trials for BE screening. The risks associated with this procedure are extremely low with a risk of severe adverse events <1:2000. Although there are no direct benefits for the individual patient, this study could benefit all ULSBE patients in the near future by reducing the need for endoscopies and by improving our ability to predict patients at higher risk of developing cancer.

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 40
Rotterdam 3015 GD
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Dr. Molewaterplein 40
Rotterdam 3015 GD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

• Any participant 18 years and above, with ULSBE and clinically fit for an endoscopy
• Ability to provide informed consent

Exclusion criteria

• Individuals with a diagnosis of an oro-pharynx, esophageal or gastro-esophageal tumor (T2 staging and above), or symptoms of dysphagia
• Esophageal varices or stricture requiring dilatation of the esophagus
• Individuals who have had a cerebrovascular event < 6 months prior where their swallowing has been affected
• Patients who have had previous treatments such as Photodynamic therapy (PDT), Radiofrequency ablation (RFA) or Argon Plasma Coagulation (APC) for dysplastic BE
• Participants who are unable to provide informed consent
• Participants under age 18 years

Study design

Design

Study phase:	4
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2024
Enrollment:	137
Type:	Anticipated

Medical products/devices used

Generic name:	EndoSign cell collection device
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	28-01-2025
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL87577.078.24