Safety and Feasibility of a Combined Sponge-Methylation Biomarker Strategy for the Detection of Premalignant and Malignant (early) Esophageal cancer.

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To assess the feasibility and safety of using a combined sponge-methylation biomarker strategy in detection of Barrett*s Esophagus, (early) esophageal cancer and detection of locoregional regrowth after nCRT.

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

Summary

ID

NL-OMON52019

Source
ToetsingOnline

Brief title
EsophaCap feasibility study

Condition

- Malignant and unspecified neoplasms gastrointestinal NEC

Synonym
Barrett Esophagus, esophageal atresia and esophageal cancer.

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

Intervention

Keyword: Esophageal cancer, Methylated biomarker, Sponge-on-a-string device, Surveillance

Outcome measures

Primary outcome

To assess the accuracy (defined as sensitivity and specificity) of diagnosis

with the EsophaCap sponge and an assay of selected methylated markers

Secondary outcome

To assess the accuracy, safety and tolerability of the combined

sponge-methylation biomarker strategy; including the rate of successful

retrievals of the EsophaCap (defined as retrieval of the complete EsophaCap

sponge, from the stomach back into the mouth), the extracted DNA yield, a

mucosal injury score, a tolerability assessment, and the preference of patients

in relation to upper endoscopy.

Study description

Background summary

Esophageal adenocarcinoma (EAC) and esophageal squamous cell carcinoma (ESCC) are associated with a very poor 5 year survival rate of less than 20%. Early detection is highly desirable since it is associated with improved survival rates. Conventional endoscopy with biopsy remains the standard procedure for early detection of esophageal cancer in patients at risk for malignant progression, such as in patients with Barrett*s esophagus (BE) and esophageal atresia (EA). Furthermore, timely detection of locoregional esophageal cancer regrowth is important for patients who undergo active surveillance after neoadjuvant chemoradiotherapy (nCRT). In all these patients, endoscopies have impact on patients* burden and endoscopy capacity. Furthermore, the cost-effectiveness of these procedures is uncertain.

Overall, there is an urgent need to develop other surveillance methods for detection of early esophageal cancer and detection of locoregional disease after nCRT. Esophageal cytology devices, such as the EsophaCap, have been studied as a non-endoscopic way to detect esophageal cancer. The EsophaCap is a non-invasive device that comprises a small sponge-containing capsule on a string, which is swallowed by the patient. After contact with the stomach the capsule dissolves and releases the sponge, which is then retrieved along the esophagus and collects cytologic material from the esophageal mucosa. This cytologic material is then available for diagnostic analyses. Studies have shown that methylation biomarkers can be used to detect Barrett*s Esophagus (BE), high-grade dysplasia (HGD), and both EAC and ESCC. Applying the use of methylation biomarkers on cytological material provided by the EsophaCap may allow effective surveillance of BE and early detection of esophageal cancer, but such approaches must be accurate, well-tolerated and safe.

Study objective

To assess the feasibility and safety of using a combined sponge-methylation biomarker strategy in detection of Barrett*s Esophagus, (early) esophageal cancer and detection of locoregional regrowth after nCRT.

Study design

Interventional prospective pilot study.

Study burden and risks

Data are collected during one visit, there is no follow-up. Patients will swallow the EsophaCap immediately prior to their scheduled upper endoscopy. After this procedure, participants will be asked to fill in a short questionnaire. Previous studies show that there are minimal risks to using the EsophaCap. The main burden for patients includes discomfort while swallowing the device, but an excellent overall median tolerability score of 2 (on a scale of 0-10, where 0 is extremely well tolerated and 10 is the worst tolerated) was observed in a previous study with Barrett patients. If the string is accidentally cut, the sponge will not cause any harm to the patient since the sponge can be removed during upper endoscopy or, if removal is unsuccessful, will naturally be excreted with the faeces. The results from the EsophaCap study will not be shared with the patient nor their treating physician. Therefore, the outcomes of the EsophaCap procedure will not have any effect on treatment or surveillance strategies. Treatment and follow-up of patients will not differ from patients who are not enrolled in this study.

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

To be eligible to participate in this study, a subject must meet all of the following criteria:
* Diagnosed with esophageal atresia OR Barrett*s Esophagus OR newly diagnosed esophageal cancer OR patients with locally advanced esophageal cancer who are in active surveillance after nCRT.
* Undergo endoscopic surveillance with biopsies at the Erasmus University Medical Center.
* Age above 18 years.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
* Patients with difficulties swallowing medication or with eating solid foods
* Patients with a nasogastric tube.
* Patients with esophageal strictures disabling passage of the capsule.
* Patients with esophageal stents.
* Patients who have undergone esophagectomy.
* Patients with extra-esophageal malignancies including head, neck and gastric cancer.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-05-2022
Enrollment:	100
Type:	Anticipated

Medical products/devices used

Generic name:	EsophaCap
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	25-10-2022

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	NL77979.078.22