

Improved screening of esophageal cancer by optical detection of field cancerization.

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1. Evaluate the feasibility of ESS for detection of field cancerization in BE patients. 2. Investigate the biological background of field cancerization by studying: a) (ultra)structural changes in the tissue and b) genetic abnormalities and clonal...

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

Summary

ID

NL-OMON43548

Source

ToetsingOnline

Brief title

SPECTRE

Condition

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

Synonym

1. Malignant cells in Barrett's esophagus. 2. Field carcinogenesis.

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Alpe d'HuZes / KWF program grant

Intervention

Keyword: Barrett's esophagus, Esophageal adenocarcinoma, Field carcinogenesis, Spectroscopy

Outcome measures

Primary outcome

1. Differences between in-vivo ESS data from neoplastic areas and non-neoplastic areas.
2. Differences between in-vivo ESS data from normal areas of patients with neoplasia vs. normal areas from patients without neoplasia.
3. Comparison of in-vivo ESS data with structural information from OCT-images and the attenuation coefficient (μ_{opt}).
4. Comparison of in-vivo MDSFR spectroscopic data with genetic abnormalities and clonal diversity detected with brush cytology and DNA FISH.

Secondary outcome

n.v.t.

Study description

Background summary

Esophageal adenocarcinoma (EAC) is a deadly disease with a poor prognosis at advanced stage. When detected in early stage, disease can be managed by minimal invasive endoscopic treatment, thereby avoiding surgery and/or chemo-radiation-therapy. Patients with Barrett's esophagus (BE) have an increased risk for developing EAC and therefore undergo regular endoscopic surveillance. These surveillance programs are hampered with several problems that compromise efficacy and cost-effectiveness. Thus new technologies for improving risk stratification for BE patients are dearly needed. Field cancerization is based on the concept that focal cancers arise in mucosa or tissue areas (*field*) with random genetic changes. Recent studies have suggested that light scattering spectroscopy is able to detect this field

carcinogenesis by measuring the light scattering properties of tissue in vivo using small fiberoptic catheters. Optical spectroscopy may, therefore, be an innovative approach to improve detection of prevalent neoplasia in BE and to identify BE patients at risk for malignant progression in the future. Elastic Scattering Spectroscopy, ESS, is a specific form of optical spectroscopy that uses optical fibres.

In this study, ESS will be combined with Optical Coherence Tomography (OCT), an imaging technique also based on scattering of light. The combination of ESS and OCT will enable better documentation of the specific locations where the measurements are taken, but also to quantify the light scattering properties of the tissue in an independent way.

We will compare our spectroscopic data with brush cytology and multicolor DNA fluorescent in situ hybridization DNA (FISH), a technique to assess genetic changes in cytology specimens.

Risk stratification of BE patients based on the detection of field-carcinogenesis with spectroscopy has several theoretically advantages for improving the cost-effectiveness of BE surveillance:

1. Spectral diagnostic probes can be reusable, easily cleaned, sustainable and cheap.
2. Data acquisition is rapid and real-time.
3. No particular training in image analysis is necessary, since data are automatically acquired and analyzed, and the reading is objective (positive or negative).
4. Tissue characteristics otherwise not visualized on histology can be assessed (chemical composition, tissue ultrastructure).
5. Enables direct decision making during ongoing endoscopy.
6. Only a small part of the organ has to be sampled, allowing for low-complex, minimal invasive screening avoiding obtaining numerous biopsy samples and decrease patient burden.

Study objective

1. Evaluate the feasibility of ESS for detection of field cancerization in BE patients.
2. Investigate the biological background of field cancerization by studying:
a) (ultra)structural changes in the tissue and b) genetic abnormalities and clonal diversity.

Study design

This study will consist of two phases: a pilot-phase, in which we will use two separate optical fibres, and a second phase, in which we will use a dual core fibre.

Study burden and risks

Spectroscopy is non-invasive in nature. The type of light delivered by the optical probe is equivalent in intensity to the standard light source used in delivered by an standard endoscope; the excitation of tissue by the light energy delivered by spectroscopy systems that are used in-vivo is non-damaging and does not result in any thermal effects on tissue. During this study patients will undergo extra spectroscopy measurements and cytology-brush. Standard clinical practice according to diagnosis and treatments is not influenced by these additional spectroscopy measurements. For study purposes, two extra biopsies will be obtained, in addition to random biopsies according to general practice. The endoscopy will take 15 minutes longer compared to the standard endoscopy for the additional spectroscopy measurements and cytology-brush.

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 referred for endoscopic treatment of early neoplasia in a Barrett's esophagus or patients undergoing standard endoscopic surveillance for non-dysplastic Barrett's esophagus.
- Age > 18 years.
- Signed informed consent.

Exclusion criteria

- Contraindications for ER and/or obtain biopsies (e.g. due to anticoagulation, coagulation disorders, esophageal varices).
- Presence of an advanced lesion (e.g. type 0-I or type 0-III) not amenable for endoscopic resection (T1b).
- Presence of erosive esophagitis (Los Angeles classification \geq A).
- Unable to provide signed informed consent.

Study design

Design

Study phase:	2
Study type:	Observational invasive
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	04-04-2016
Enrollment:	60
Type:	Actual

Medical products/devices used

Generic name:	IVS 2000 (Santec ;Aichi;Japan) interfaced to a
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Registration: SM1250(10.4/125)P optical fiber (FIBERCORE;Southampto
Yes - CE outside intended use

Ethics review

Approved WMO
Date: 24-02-2016
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	NL55733.018.15