

SPECTRE-study

No registrations found.

| | |
|------------------------------|----------------------------|
| Ethical review | Positive opinion |
| Status | Recruitment stopped |
| Health condition type | - |
| Study type | Observational non invasive |

Summary

ID

NL-OMON21436

Source

Nationaal Trial Register

Brief title

SPECTRE

Health condition

Barrett's esophagus, esophageal cancer, field cancerization

Sponsors and support

Primary sponsor: Academic Medical Center (AMC) Amsterdam

Source(s) of monetary or material Support: KWF grant

Intervention

Outcome measures

Primary outcome

The primary objective of our study is to evaluate the feasibility of using MDSFR combined with OCT for the detection of field cancerization in Barrett esophagus patients.

Secondary outcome

The secondary objective is to investigate the biological background of field cancerization detected by ESS

Study description

Background summary

Barrett's esophagus (BE) is a precursor lesion for esophageal adenocarcinoma. Therefore, the current Barrett's surveillance protocol consists of white light endoscopy and random biopsies. Field cancerization is based on the concept that focal cancers arise in tissue areas with random genetic changes. Light scattering spectroscopy might be able to detect this field cancerization and therefore be an innovative approach to improve detection of prevalent neoplasia in BE patients.

In this study, we will evaluate the feasibility of optical detection of field cancerization in BE patients.

Study objective

Screening of esophageal cancer can be improved by the optical detection of field cancerization

Study design

not applicable

Intervention

Optical measurements will be performed on several locations in the esophagus. Biopsies will also be obtained. Brush cytology will be obtained.

Contacts

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Eligibility criteria

Inclusion criteria

- Age > 18 years.
- Known BE, defined as columnar lined epithelium of the esophagus containing intestinal metaplasia upon biopsy.
- 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 amendable for endoscopic resection (T1b).
- Presence of erosive esophagitis (Los Angeles classification ≥ A).
- Unable to provide signed informed consent.

Study design

Design

| | |
|---------------------|----------------------------|
| Study type: | Observational non invasive |
| Intervention model: | Other |
| Allocation: | Non controlled trial |
| Masking: | Open (masking not used) |
| Control: | N/A , unknown |

Recruitment

| | |
|---------------------|---------------------|
| NL | |
| Recruitment status: | Recruitment stopped |

| | |
|---------------------------|------------|
| Start date (anticipated): | 04-04-2016 |
| Enrollment: | 60 |
| Type: | Actual |

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

| | |
|-------------------|------------------|
| Positive opinion | |
| Date: | 15-03-2016 |
| Application type: | First submission |

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 |
|----------|---------------------------------------|
| NTR-new | NL5628 |
| NTR-old | NTR5735 |
| Other | AMC METC 2015_323 : AMC METC 2015_323 |

Study results

Summary results

None yet