Acetic acid chromoendoscopy for detection of neoplastic Barrett's esophagus

No registrations found.

Ethical review Positive opinion

Status Pending

Health condition type -

Study type Observational non invasive

Summary

ID

NL-OMON25059

Source

Nationaal Trial Register

Brief title

ACID

Health condition

Barrett's esophagus

Sponsors and support

Primary sponsor: St. Antonius Hospital

Source(s) of monetary or material Support: St. Antonius Onderzoeksfonds

Intervention

Outcome measures

Primary outcome

Overall neoplasia detection rate (defined as the percentage of patients with either targeted or standardized random biopsies containing LGD, HGD or EAC).

Secondary outcome

- 1. Neoplasia detection rate stratified by degree of neoplasia in biopsies (LGD, HGD, EAC).
- 2. Neoplasia detection rate in of targeted biopsies only (defined as the percentage of patients with targeted biopsies containing LGD, HGD and EAC).
- 3. Duration of endoscopy.

Study description

Background summary

Barrett's esophagus (BE) is a premalignant condition, predisposing to esophageal adenocarcinoma (EAC). Because of this predisposition, current guidelines recommend surveillance endoscopies for patients with BE with targeted biopsies in case of mucosal abnormality, followed by random 4-quadrantic biopsies every 2 centimeter of the Barrett's length according to the Seattle protocol. The use of acetic acid chromoendoscopy (AAC) in regular BE surveillance is controversial, and across Europe, some centers use it on a routine base, whereas other centers never use it. Recent research suggests that AAC might increase the neoplasia yield in high risk patients when procedures were carried out by expert endoscopists. However, the added value of AAC in routine Barrett's surveillance, when carried out in routine clinical practice in unselected patients without a history of dysplasia or EAC, remains unknown.

Therefore, the objective of this study is to evaluate whether AAC-guided endoscopy increases the neoplasia detection rate compared to conventional surveillance endoscopy in patients with Barrett's esophagus in routine clinical practice.

This is a multicenter, prospective, stepped wedge cluster randomized study.

Study objective

AAC-guided endoscopy increases the neoplasia detection rate compared to conventional surveillance endoscopy in patients with Barrett's esophagus in routine clinical practice.

Study design

N/A

Intervention

Acetic acid chromoendoscopy

Contacts

Public

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Scientific

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Eligibility criteria

Inclusion criteria

- 18 years of age or older
- Diagnosis of Barrett's esophagus undergoing surveillance gastroscopy
- Signed consent for the use of patient data

Exclusion criteria

- Previous treatment for esophageal neoplasia (endoscopic resection, photodynamic therapy, argon plasma coagulation, radiofrequency ablation)
- Referral from other centers with suspected or known dysplasia for assessment and endoscopic intervention
- Obvious visible cancers at gastroscopy other than esophageal adenocarcinoma (i.e. gastric cancer, or esophageal squamous cell carcinoma)
- Known dysplasia or intensified endoscopic surveillance because of previously diagnosed dysplasia
- Prior esophagectomy
- Active esophagitis LA grade C or higher, precluding endoscopic biopsies (patients can be included after adequate treatment)
- Esophageal varices precluding endoscopic biopsies
- Coagulation disorders precluding endoscopic biopsies
- Allergy to acetic acid

Study design

Design

Study type: Observational non invasive

Intervention model: Other

Allocation: Randomized controlled trial

Masking: Open (masking not used)

Control: N/A , unknown

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-01-2020

Enrollment: 3268

Type: Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date: 04-12-2019

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 NL8214

Other MEC-U: W19.107

Study results