# 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

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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