

# Acetic acid chromoendoscopy for detection of neoplastic Barrett's esophagus

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

|                             |                                                     |
|-----------------------------|-----------------------------------------------------|
| <b>Ethische beoordeling</b> | Positief advies                                     |
| <b>Status</b>               | Werving nog niet gestart                            |
| <b>Type aandoening</b>      | -                                                   |
| <b>Onderzoekstype</b>       | Observationeel onderzoek, zonder invasieve metingen |

## Samenvatting

### ID

NL-OMON25059

### Bron

Nationaal Trial Register

### Verkorte titel

ACID

### Aandoening

Barrett's esophagus

### Ondersteuning

**Primaire sponsor:** St. Antonius Hospital

**Overige ondersteuning:** St. Antonius Onderzoeksfonds

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

#### Primaire uitkomstmaten

Overall neoplasia detection rate (defined as the percentage of patients with either targeted

or standardized random biopsies containing LGD, HGD or EAC).

## Toelichting onderzoek

### Achtergrond van het onderzoek

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.

### Doel van het onderzoek

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

### Onderzoeksopzet

N/A

### Onderzoeksproduct en/of interventie

Acetic acid chromoendoscopy

## Contactpersonen

## **Publiek**

St. Antonius Ziekenhuis  
Ilse Beaufort

088-3206043

## **Wetenschappelijk**

St. Antonius Ziekenhuis  
Ilse Beaufort

088-3206043

## **Deelname eisen**

### **Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)**

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

### **Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)**

- 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

## Onderzoeksopzet

### Opzet

|                  |                                                     |
|------------------|-----------------------------------------------------|
| Type:            | Observationeel onderzoek, zonder invasieve metingen |
| Onderzoeksmodel: | Anders                                              |
| Toewijzing:      | Gerandomiseerd                                      |
| Blinding:        | Open / niet geblindeerd                             |
| Controle:        | N.v.t. / onbekend                                   |

### Deelname

|                         |                          |
|-------------------------|--------------------------|
| Nederland               |                          |
| Status:                 | Werving nog niet gestart |
| (Verwachte) startdatum: | 01-01-2020               |
| Aantal proefpersonen:   | 3268                     |
| Type:                   | Verwachte startdatum     |

### Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

**Wordt de data na het onderzoek gedeeld:** Nog niet bepaald

## Ethische beoordeling

|                 |                  |
|-----------------|------------------|
| Positief advies |                  |
| Datum:          | 04-12-2019       |
| Soort:          | Eerste indiening |

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register       | ID              |
|----------------|-----------------|
| NTR-new        | NL8214          |
| Ander register | MEC-U : W19.107 |

## Resultaten