

# Anti-reflux mucosectomy (ARMS) for gastroesophageal reflux disease: efficacy and mechanism of action

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Efficacy and working mechanism of ARMS

|                             |                       |
|-----------------------------|-----------------------|
| <b>Ethische beoordeling</b> | Positief advies       |
| <b>Status</b>               | Werving gestart       |
| <b>Type aandoening</b>      | -                     |
| <b>Onderzoekstype</b>       | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON28707

### Bron

Nationaal Trial Register

### Verkorte titel

ARMS - trial

### Aandoening

Reflux disease

### Ondersteuning

**Primaire sponsor:** Amsterdam UMC

**Overige ondersteuning:** None

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

#### Primaire uitkomstmaten

The total number of (acidic, weakly acidic and gas) gastroesophageal reflux episodes, as measured during 24-hour pH-impedance monitoring.

# Toelichting onderzoek

## Achtergrond van het onderzoek

**Rationale:** A substantial part of patients with gastroesophageal reflux disease (GERD) responds insufficiently to pharmacological therapy. In search of non-surgical treatment methods in this patient group, a novel anti-reflux endoscopic procedure - anti-reflux mucosectomy (ARMS) - has been developed. Although previous studies suggest that ARMS is effective in reducing symptoms and total acid exposure, the effects of the procedure on the number of reflux episodes and the mechanisms through which reflux control is achieved have not been investigated.

**Objective:** To investigate the efficacy and the mechanisms of action of an anti-reflux mucosectomy in patients with gastroesophageal reflux disease.

**Study design:** A prospective therapeutic intervention study

**Study population:** 11 adult patients with gastroesophageal reflux disease confirmed by pH-impedance measurement.

**Intervention (if applicable):** All subjects will undergo ARMS. Reflux activity will be measured at baseline and at 3 months follow-up with both ambulatory and prolonged postprandial stationary pH-impedance measurements. Concomitantly, the occurrence of transient lower esophageal sphincter relaxations (TLESRs) will be studied during a prolonged postprandial stationary manometry. The distensibility of the esophagogastric junction will be assessed with EndoFLIP. Furthermore, patients will undergo a follow-up endoscopy 3 months after ARMS.

**Main study parameters/endpoints:** The main study parameter is the total number of reflux episodes assessed during ambulatory 24-h pH-impedance studies. Secondary endpoints include total 24-h acid exposure time, prevalence of TLESRs, EGJ morphology and distensibility, grade of reflux esophagitis and hiatal hernia, symptoms and quality of life scores and procedure-related complications.

## Doel van het onderzoek

Efficacy and working mechanism of ARMS

## Onderzoeksopzet

Baseline and follow-up at 3 months

## Onderzoeksproduct en/of interventie

Anti-reflux mucosectomy

## Contactpersonen

### Publiek

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### Wetenschappelijk

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## Deelname eisen

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

- Indication for surgical treatment, defined by objectively confirmed gastroesophageal reflux disease (24-h ambulatory pH-impedance study with a symptom association probability  $\geq 95\%$ ; and esophageal acid exposure  $\geq 4\%$ )
- Symptoms of heartburn, regurgitation and/or chest pain under PPI-treatment for at least 3 months at least 3 times a week.
- Use of proton pump inhibitors at a standard dose twice a day for at least 4 weeks prior to inclusion.

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

- ASA classification of III or higher.
- Previous (surgical or endoscopic) anti-reflux procedure
- Previous surgery of the stomach or esophagus
- Sliding hiatal hernia  $> 2\text{cm}$
- Esophagitis grade C or D
- Presence of Barrett's esophagus with dysplasia
- Known coagulopathy
- Unable to stop coagulants (with the exception of mono antiplatelet therapy)
- Presence of liver cirrhosis and/or esophageal varices

- Presence of a stricture of the esophagus
- Presence of eosinophilic esophagitis
- Presence of achalasia
- Presence of connective tissue disorder
- Absent peristalsis on high-resolution manometry
- Pregnancy at time of treatment

## Onderzoeksopzet

### Opzet

|                  |                         |
|------------------|-------------------------|
| Type:            | Interventie onderzoek   |
| Onderzoeksmodel: | Anders                  |
| Toewijzing:      | N.v.t. / één studie arm |
| Blinding:        | Open / niet geblindeerd |
| Controle:        | N.v.t. / onbekend       |

### Deelname

|                         |                      |
|-------------------------|----------------------|
| Nederland               |                      |
| Status:                 | Werving gestart      |
| (Verwachte) startdatum: | 17-12-2019           |
| Aantal proefpersonen:   | 11                   |
| 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:          | 17-12-2019       |
| 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        | NL8246                  |
| Ander register | METc AMC : METC2019_145 |

## Resultaten