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

Gepubliceerd: 17-12-2019 Laatst bijgewerkt: 18-08-2022

Efficacy and working mechanism of ARMS

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	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

Amsterdam UMC
Renske Oude Nijhuis

+31205667805

Wetenschappelijk

Amsterdam UMC
Renske Oude Nijhuis

+31205667805

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 ≥95%; and esophageal acid exposure ≥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 >2cm
- 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
Blindering:	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