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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28707

Source
Nationaal Trial Register

Brief title
ARMS - trial

Health condition

Reflux disease

Sponsors and support

Primary sponsor: Amsterdam UMC
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

To study the effect of anti-reflux mucosectomy on:
- Total, upright and supine acid exposure time during 24-hour pH-impedance studies.
- The prevalence of transient lower esophageal sphincter relaxations (TLESRs) during a 90-minute postprandial stationary measurement.
- The number of acidic, weakly acidic and gas gastroesophageal reflux episodes during the 90-min postprandial stationary period.
- Manometric features of the esophagogastric junction (integrated relaxation pressure (IRP), lower esophageal sphincter resting pressure, presence of hiatal hernia) and esophageal body, as assessed with stationary high-resolution manometry.
- Esophagogastric junction distensibility measured with endoFLIP.
- Grade of the gastroesophageal flap valve, using the Hill classification.
- Grade of esophageal erosive esophagitis, using the Los Angeles classification.
- Reflux symptom score assessed by the Reflux Disease Questionnaire (RDQ).
- Quality of life scores assessed by the health-related quality of life for GERD (GERD-HRQL)
- PPI use

To describe procedure-related adverse events
- Occurrence of post-procedure strictures assessed by endoscopy at 3-months follow-up.
- Presence of dysphagia as assessed by the Brief Esophageal Dysphagia Questionnaire (BEDQ)
- Other complications of the treatment, defined as any unwanted events that arise following treatment and/or that are secondary to the treatment.

Study description

Background summary

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.

Study objective

Efficacy and working mechanism of ARMS

Study design

Baseline and follow-up at 3 months

Intervention

Anti-reflux mucosectomy

Contacts

Public
Amsterdam UMC
Renske Oude Nijhuis

+31205667805
Scientific
Amsterdam UMC
Renske Oude Nijhuis

+31205667805

Eligibility criteria

Inclusion criteria

- 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.

Exclusion criteria

- 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

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-12-2019
Enrollment:	11

Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion Date:	17-12-2019
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	NL8246
Other	METc AMC : METC2019_145

Study results