Effect of dilating the gastro-esophageal junction on prolonged dysphagia after anti-reflux operation.

No registrations found.

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

Summary

ID

NL-OMON28275

Source
Nationaal Trial Register

Brief title
DAFFODIL trial (Dysphagia After Fundoplication: eFfect Of Dilatation)

Health condition

Gastroesophageal reflux disease (GERD), Pneumodilatation (balloon dilatation), Fundoplication (anti-reflux operation), prolonged dysphagia.

Sponsors and support

Primary sponsor: Academic Medical Center Amsterdam, University of Amsterdam
Source(s) of monetary or material Support: Academic Medical Center Amsterdam, University of Amsterdam

Intervention

Outcome measures

Primary outcome

Dysphagia symptom severity (Eckardt score)

Secondary outcome

• Reflux symptom severity (Reflux disease questionnaire; RDQ)

• Health related Quality of life (SF-36)

• Impaction dysphagia questionnaire (IDQ)

• Height and width of stasis on barium esophagogram after one minute

• High-resolution manometry (LES pressure, IRP-4)

• Adverse events / complications

• Change in body weight

Study description

Background summary

Rationale: The prevalence of gastroesophageal reflux disease (GERD) is 10-20% in the western world. Typical symptoms are heartburn and regurgitation. The most effective treatment is laparoscopic fundoplication, in which the fundus of the stomach (partially) placed around the distal esophagus. Postoperative dysphagia is usually self-limiting within 2-6 weeks. In 5-10% of patients however, prolonged dysphagia is seen (> 3 months postoperatively). Treatment options are an expectative approach or dilation of the lower esophageal sphincter and surgically constructed wrap around it. Pneumodilation (PD) is generally believed to be the most effective dilatation technique, but it has never been shown that dilation of the LES and wrap is actually more effective than the expectative approach.

Objective: To evaluate the effect of pneumodilatation (PD) on prolonged dysphagia after Toupet or Nissen fundoplication compared to sham dilatation.
Study design: This is an interventional, multicentre trial. Either pneumodilatation or sham dilation is performed in a randomized, single-blinded manner.

Study population: 42 adult patients with prolonged dysphagia (> 3 months) after primary Nissen or Toupet fundoplication for GERD.

Intervention: In one group a pneumodilatation is performed and in the other group a sham dilatation (endoscopy without intervention) is performed .
Main study endpoints: Dysphagia symptom severity (Eckardt score).

Study objective

The aim of the study is to compare the efficacy of pneumodilatation with 'sham'-treatment (placebo intervention). It is hypothesized that pneumodilatation will resolve dysphagia faster than sham dilatation.

Study design

Baseline: high-resolution manometry, barium esophagography, informed consent, questionnaires

Day 1 (visit 1): Endoscopy with pneumodilatation or sham dilatation

Day 7: Questionnaires by telephone or mail.

Day 30 (visit 2): high-resolution manometry, barium esophagography, questionnaires

Questionnaires are: Eckardt score, Short form-36 (health related quality of life), Reflux disease questionnare (RDQ), Impaction dysphagia questionnaire (IDQ)

Intervention

Patients with persistent dysphagia more than 3 months postoperatively will be randomized to either pneumatic dilatation or to sham dilatation.

Pneumatic dilatation: During endoscopy under sedation. The Rigiflex 35 mm balloon will be positioned in the lower esophageal sphincter (LES) area (x-rays can be used or this can be done under direct endoscopic guidance) and inflated to 35mm at 8 psi and maintained until the “waist” of the balloon is obliterated, or for at least one minute.

Sham dilatation: This endoscopy will also be performed under sedation. However, no dilatation or other intervention will be performed.

The patient is blinded to the treatment.

Participating sites:

- Academic Medical Center, Amsterdam

- Meander Medical Center, Amersfoort

- University Hospital Leuven, Leuven

- Maastricht University Medical Center, Maastricht

- St Antonius Hospital, Nieuwegein

Contacts

Public
Meibergdreef 9
A.J. Bredenoord
Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5661745
Scientific
Meibergdreef 9
A.J. Bredenoord
Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5661745

Eligibility criteria

Inclusion criteria

• Patients after primary Nissen or Toupet fundoplication for GERD

• Dysphagia that was not present before surgery and lasting for at least 3 months

• Eckardt symptom score ≥ 4

• Written informed consent

• Age above 18 years

Exclusion criteria

• Significant dysphagia before surgery

• Previous dilatation for dysphagia

• History of (pseudo)achalasia

• Anatomical defects causing dysphagia (slipped, malpositioned or herniated fundoplication)

• Allergy to barium sulfate

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-04-2015
Enrollment:	42
Type:	Anticipated

Ethics review

Positive opinion

Date:	10-06-2015
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 47334
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5115
NTR-old	NTR5247
CCMO	NL50376.018.14
OMON	NL-OMON47334

Study results

Summary results
N/A