Effect of pneumodilatation in patients with prolonged dysphagia after antireflux surgery

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To evaluate the effect of pneumodilatation (PD) on prolonged dysphagia after Toupet or Nissen fundoplication compared to sham dilatation.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal motility and defaecation conditions
Study type	Interventional

Summary

ID

NL-OMON47334

Source
ToetsingOnline

Brief title
DAFFODIL STUDY: Dysphagia After Fundoplication: eFfect Of DILatation

Condition

- Gastrointestinal motility and defaecation conditions

Synonym
difficulty in swallowing after anti-reflux surgery, Postfundoplication dysphagia

Research involving
Human

Sponsors and support

Primary sponsor: Maag-, Darm- en Leverziekten
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Dysphagia, Fundoplication, Gastroesophageal reflux disease, Pneumodilatation

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)

-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

The most effective treatment for refractory gastro-esophageal reflux disease (GERD) is laparoscopic fundoplication, in which the fundus of the stomach is totally (Nissen fundoplication) or partially (Toupet fundoplication) placed around the distal part of the esophagus. Postoperative dysphagia, a common side-effect after these operations, is usually self-limiting and generally disappears after 2-6 weeks. In 5-10% of patients however, prolonged dysphagia is seen, defined as lasting more than three months postoperatively. There is no evidence-based treatment for prolonged dysphagia after antireflux surgery, but the options are an expectative approach or dilation of the lower esophageal sphincter (LES) and surgically constructed wrap around it with a balloon (pneumodilatation) or bougie (Savary dilatation). Pneumodilation 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.

Study objective

To evaluate the effect of pneumodilatation (PD) on prolonged dysphagia after Toupet or Nissen fundoplication compared to sham dilatation.

Study design

A prospective, multicentre, single-blind, randomized, sham-controlled intervention study.

Intervention

One group receives a pneumatic dilation (once), and one group receives a sham-dilation (endoscopy without intervention).

Study burden and risks

In this study, we evaluate the hypothesis that treatment of patients with prolonged dysphagia after fundoplication by balloon dilatation is more effective than sham dilatation. Benefits of treatment are potential dysphagia relief by a minimally invasive procedure in an outpatient setting, with minimal pain and only a minimal chance to develop GERD. It has been described that pneumatic dilation has a positive effect on postoperative dysphagia. However, it has never been compared to sham dilatation. As it is currently not known whether balloon dilatation is indeed beneficial, the benefit of the study participation is uncertain. Risks of participation could be bleeding or perforation, if pneumodilatation is performed. These risks however, also occur when it is decided to perform pneumatic dilatation as regular treatment. In case of complications, the gastroenterologist will decide to re-intervene endoscopically. The risk of sham dilatation is continuing dysphagia and concomitant weight loss and pain. The burden of participating patients will be one extra phone call and filling out questionnaires three times. Moreover, for the patients of the sham-group, an endoscopy will be performed, while normally no intervention would be performed in this group of patients given that they receive no treatment. No extra visits or investigations are necessary, for all other investigations (HRM, barium esophagogram) are part of the normal work-up for these patients.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

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
*Informed consent
*Age above 18 years

Exclusion criteria

*Significant dysphagia before surgery
*Previous dilatation for dysphagia
*History of (pseudo)achalasia
*Anatomical defects causing dysphagia
*Allergy to barium sulfate

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-03-2015
Enrollment:	34
Type:	Actual

Medical products/devices used

Generic name:	Balloon dilator
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	16-10-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	30-01-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 28275
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL50376.018.14
OMON	NL-OMON28275