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

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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.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28275

Bron
Nationaal Trial Register

Verkorte titel
DAFFODIL trial (Dysphagia After Fundoplication: eFfect Of Dilatation)

Aandoening

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

Ondersteuning

Primaire sponsor: Academic Medical Center Amsterdam, University of Amsterdam
Overige ondersteuning: Academic Medical Center Amsterdam, University of Amsterdam

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Dysphagia symptom severity (Eckardt score)

Toelichting onderzoek

Achtergrond van het onderzoek

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).

Doel van het onderzoek

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.

Onderzoeksopzet

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)

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Placebo

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-04-2015
Aantal proefpersonen:	42
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	10-06-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 47334

Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A