The TOUCAN trial: a randomised, blind, clinical trial that compares the effects of TOUpet fundopliCAtion and Nissen fundoplication on the mechanics of the gastroesophageal junction.

Published: 29-09-2009
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To identify differences in the mechanisms leading to dysphagia after laparoscopic Toupet and Nissen fundoplication.

Ethical review	Not approved
Status	Will not start
Health condition type	Gastrointestinal therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON33114

Source
ToetsingOnline

Brief title
TOUCAN trial

Condition

- Gastrointestinal therapeutic procedures

Synonym
Gastroesophageal reflux, reflux disease

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Dysphagia, Gastroesophageal reflux disease, Nissen fundoplication, Toupet fundoplication

Outcome measures

Primary outcome

Residual relaxation pressure of the EGJ on high-resolution manometry.

Secondary outcome

1. Dysphagia (Mayo Dysphagia Questionaire)

2. Esophageal transit time

- Esophageal transit time and esophageal diameter on timed barium esophagram

- Esophagogastric transit time on impedance monitoring

3. Esophageal motility on high-resolution manometry

4. Compliance of the EGJ, quantified as the cross-sectional area of EGJ after

volume controlled distension, using a Functional Lumen Imaging Probe (FLIP)

5. Severe dysphagia, defined as: dysphagia needing reintervention (balloon

dilatation or surgical reintervention), causing weight loss or requiring diet

changes.

6. Reflux symptoms (RDQ)

7. Quality of Life (SF-36)

Study description

Background summary

Gastroesophageal reflux disease (GERD) is a chronic disease with a high-prevalence. GERD refractory to acid suppression, with a documented relation between symptoms and reflux episodes, is a well accepted indication for antireflux surgery. Total, or Nissen, fundoplication is the most frequently performed surgical therapy for medication refractory GERD. This laparoscopic procedure creates a wrap of the proximal stomach around the distal esophagus and ensures superior reflux control. The most important complication of this therapy is the development of persistent esophageal passage disorders (dysphagia) in a considerable number of patients. An alternative therapy is partial Toupet fundoplication, a procedure that creates a partial, 270 degree, wrap of the stomach around the distal esophagus.
Dysphagia occurs less frequently after Toupet fundoplicatie than after Nissen fundoplication. Despite this, Nissen fundoplication is the most frequently performed antireflux procedure worldwide, since it is controversial whether Toupet fundoplication equals reflux control after Nissen fundoplication. These differences require further research, since there is currently no consensus about which procedure is the surgical therapy of choice. Dysphagia severely impairs quality of life and often requires surgical reintervention. Therefore, it is important to identify differences in the mechanisms leading to dysphagia after Toupet and Nissen fundoplication. If the results of the current study will give sufficient insight into the differences in the mechanisms leading to dysphagia, this could be the starting point of a subsequent study investigating which modifications of the Nissen fundoplication reduce the incidence of this important complication.

Study objective

To identify differences in the mechanisms leading to dysphagia after laparoscopic Toupet and Nissen fundoplication.

Study design

Randomized, blind, clinical multicenter trial

Intervention

After randomization, twenty-five patients will undergo laparoscopic Toupet fundoplication and will be compared to twenty-five patients who will undergo laparoscopic Nissen fundoplication.

Study burden and risks

Similar to all patients that may have an indication for antireflux surgery, the patients that participate will undergo a preoperative upper endoscopy, barium

swallow, short manometry and 24-hr pH-impedance study. In addition, a FLIP investigation will be performed for the purpose of this study. Patients will be asked to fill out questionnaires before surgery (25 min). These questionnaires will register dysphagia, quality of life and reflux symptoms. One, three, six and twelve months after the operation, the participants will be asked to fill out the questionnaires on general quality of life, GERD symptoms and dysphagia (25 min). These questionnaires are as short as possible tot reduce the burden for the patients.

Six months after surgery routine upper endoscopy, barium swallow, short manometry and 24-hr pH-impedance study will be repeated to evaluate the effect of fundoplicaton. In addition, a FLIP investigation will be performed for the purpose of this study. All these investigations are safe and complications are rare. The department of surgery of the UMC Utrecht has conducted three large follow-up studies, investigating the subjective and objective results of Nissen fundoplication in a similar way. This research has demonstrated that the postoperative complaints reported by patient do not correlate with reflux episodes. Therefore, routine objective follow-up is essential. The postoperative investigations will be similar to the previously mentioned studies. These investigations are a considerable burden for the patients, but in our experience, patients are willing to undergo these additional tests.

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

- Persisting reflux related complaints for over 6 months despite double dose PPI use (* 40 mg omeprazole / 24 hours or comparable therapy) and/or refusal of taking lifelong antireflux medication.
- Pathological ambulatory 24 hour pH test (total acid exposure > 5.8% and/or symptom association probability (SAP) > 95%)
- Adults
- Healthy patients with no disease other than the disorder for which the operations carried out and patients with mild to moderate systemic disease caused by the surgical condition or by other pathological processes, medically well-controlled (American Society of Anaesthesiologists classification of preoperative risk 1 or 2)

Exclusion criteria

- History of gastric or esophageal surgery
- Esophageal aperistalsis
- Achalasia
- Esophageal spasms
- Contraindications against undergoing laparoscopic antireflux surgery
- Patients with a psychiatric disease or other conditions making them incapable of filling out the questionnaires or completing the esophageal function tests.

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	50
Type:	Anticipated

Ethics review

Not approved

Date:	29-09-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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
CCMO	NL28697.041.09