MANTA/TRIAL, Randomized Clinical Trial of Laparoscopic Toupet versus 180˚ Anterior Fundoplication for Gastroesophageal Reflux Disease

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28375

Source
NTR

Brief title
MANTA

Health condition

gastroesophageal reflux disease, fundoplication, laparoscopic surgery

Sponsors and support

Primary sponsor: St Antonius Hospital, Nieuwegein
Source(s) of monetary or material Support: Antonius Hospital, Nieuwegein

Intervention

Outcome measures

Primary outcome

Dysphagia score after 6 months

Secondary outcome

- Objective reflux control

- Gas-related symptoms

- Subjective reflux control

- Esophageal motility

- Intraluminal pressure in the region of the fundoplication

- Postoperative PPI use

- Reintervention for dysphagia or recurrent reflux disease

- Patient satisfaction

- Major complications

- duration of operation

- in-hospital stay

- minor complications, including superficial wound infection, urinary tract infection, bleeding without need for blood transfusion or re-intervention.

Study description

Background summary

Rationale: Laparoscopic partial fundoplications for gastroesophageal reflux disease like Toupet and Anterior fundoplication ensure long-term reflux control and reduce the risk of troublesome side effects. It is unclear which of both partial fundoplications is superior.

Objective: To define the optimum laparoscopic anti-reflux operation, ensuring long-term reflux control with minimal postoperative dysphagia and gas-related symptoms.

Study design: Multicenter prospective blinded randomized clinical superiority trial comparing two laparoscopic procedures for gastroesophageal reflux disease.

Study population: Adult patients with objectified gastroesophageal reflux disease proven by either endoscopy or 24 hour pH monitoring.

Intervention: Patients will be randomized to undergo a laparoscopic Toupet or Anteriour fundoplication. Both operations are clinically accepted operations according to standard clinical indications.

Main study parameters/endpoints: Objective reflux control, dysphagia and gas related symptoms are the main study endpoints. Patients will undergo prior to the surgery a manometry and 24 hour pH monitoring or combined pH-impedance monitoring similar to normal clinical practice. Questionnaires will be filled in pre-operatively and at 1, 3, 6, 12 months post-operatively and then yearly for up to 20 years. Furthermore undergo patients similar to normal post-operative follow-up a endoscopy, pH monitoring or combined pH-impedance and manometry at 3 months after surgery.

Study objective

To define the optimum laparoscopic anti-reflux operation, ensuring long-term reflux control with minimal postoperative dysphagia and gas-related symptoms

Study design

1, 3, 6, 12 months post-operatively and then yearly.

Intervention

Patients will be randomized to undergo a laparoscopic Toupet or Anteriour fundoplication. Both operations are clinically accepted operations according to standard clinical indications.

Contacts

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Eligibility criteria

Inclusion criteria

- Age ≥ 18 years

- Proven gastroesophageal reflux disease by either endoscopy or 24 hour pH monitoring.

- Clinically indicated anti-reflux surgery

- Fit for surgery

- Reflux disease inadequately controlled by medication of unwillingness to take lifelong medication

Exclusion criteria

- Age < 18 years

- No informed consent

- Previous anti-reflux surgery

- Large hiatus hernia (more than 50% of the stomach in the chest)

- Pregnant

- Esophageal aperistalsis

- Esophageal spasms or achalasia

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-08-2012
Enrollment:	94
Type:	Actual

Ethics review

Positive opinion

Date:	26-03-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 39080
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5596

Register	ID
NTR-old	NTR5702
CCMO	NL39193.100.12
OMON	NL-OMON39080

Study results

Summary results
nvt