MANTA-TRIAL; Randomized Controlled Trial of laparoscopic Toupet versus Anterior Fundoplication for Gastroesophageal Reflux Disease

Published: 12-07-2012
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To define the optimum laparoscopic anti-reflux operation, ensuring long-term reflux control with minimal postoperative dysphagia and gas-related symptoms.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Gastrointestinal conditions NEC
Study type	Interventional

Summary

ID

NL-OMON39080

Source
ToetsingOnline

Brief title
MANTA-TRIAL

Condition

- Gastrointestinal conditions NEC
- Gastrointestinal therapeutic procedures

Synonym
dysphagia, reflux

Research involving
Human

Sponsors and support

Primary sponsor: Sint Antonius Ziekenhuis

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: dysphagia, fundoplication, gastroesophageal reflux disease, operation

Outcome measures

Primary outcome

Objective reflux control, dysphagia and gas related symptoms are the main study

endpoints.

Secondary outcome

not applicable

Study description

Background summary

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.

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

Prospective blinded randomized controlled superiority trial comparing two laparoscopic procedures for gastroesophageal reflux disease.

Intervention

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

Study burden and risks

: Included 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

Contacts

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Trial sites

Listed location countries

Netherlands

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

Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-08-2012
Enrollment:	94
Type:	Actual

Medical products/devices used

Registration:	No

Ethics review

Approved WMO

Date:	12-07-2012
Application type:	First submission

Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	14-06-2013
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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: 28375
Source: NTR
Title:

In other registers

Register	ID
CCMO	NL39193.100.12
OMON	NL-OMON28375