Randomized Controlled Trial of Laparoscopic Primary Diaphragm Repair with Sutures Alone versus Sutures Reinforced with Mesh for Hiatus Hernia.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON23150

Source
NTR

Brief title
PRIME

Health condition

Hiatus Hernia

Sponsors and support

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

Intervention

Outcome measures

Primary outcome

Integrity of the hiatal repair is the main endpoint.

Secondary outcome

Secondary objectives include clinical recurrence of the hernia, development of post-operative reflux disease, postoperative side effects and overall satisfaction with surgical outcome.

Study description

Background summary

Rationale:

Laparoscopic hiatus hernia repair is associated with a high recurrence rate. Repair reinforced with mesh lowers short-term recurrence but can cause dysphagia and visceral erosion. Previous studies evaluating lightweight polypropylene mesh (TiMesh®) for repair of hiatal hernia demonstrated good symptomatic and clinical outcome. However, recurrence rates in the long term are unknown.
Objective: To define the optimum laparoscopic hiatus hernia repair, ensuring long-term effect with minimal postoperative side effects.

Study design:

Prospective blinded randomized controlled superiority trial comparing two laparoscopic procedures for hiatus hernia repair (36 versus 36).

Study population:

Adult patients with proven hiatus hernia.

Intervention:

Patients will be randomized to undergo a laparoscopic primary repair with sutures alone or sutures augmented with prosthetic mesh.

Main study parameters/endpoints:

Integrity of the hiatal repair is the main endpoint. Secondary objectives include clinical

recurrence of the hernia, development of post-operative reflux disease, postoperative side effects and overall satisfaction with surgical outcome.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

Preoperatively included patients will undergo an endoscopy and barium meal X-ray according to standard clinical practice. Questionnaires will be filled in pre-operatively and at 3, 6, 12 months post-operatively and then yearly for up to 20 years. Patients will undergo similar to standard post-operative follow-up and including barium meal X-ray and endoscopy at 3 months and 3 years after surgery.

Study objective

To define the optimum laparoscopic hiatus hernia repair, ensuring long-term effect with minimal postoperative side effects.

Study design

Short- en longterm, 3 months and 3 years follow-up.

Intervention

Patients will be randomized to undergo a laparoscopic primary repair with sutures alone or sutures augmented with prosthetic mesh.

Contacts

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Eligibility criteria

Inclusion criteria

1. Age ≥ 18 years;

2. Hiatus hernia;

3. Laparoscopic surgical repair clinically indicated;

4. Fit for surgery;

5. Suitable for both procedures.

Exclusion criteria

1. Age < 18 years;

2. No informed consent;

3. Previous anti-reflux surgery or repair for hiatus hernia;

4. Pregnancy.

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: Pending

Start date (anticipated):	01-02-2013
Enrollment:	72
Type:	Anticipated

Ethics review

Not applicable
Application type: Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 39875
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3546
NTR-old	NTR3776
CCMO	NL42495.100.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON39875

Study results

Summary results
N/A