Randomized Controlled Trial of Laparoscopic Primary Crural Repair versus Primary Repair with Circular Bio-absorbable Hiatal Mesh Reinforcement in Hiatal Hernia Repair

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON27270

Source
Nationaal Trial Register

Brief title
PRIME-II

Health condition

Adults with giant hiatal hernia`s.

Sponsors and support

Primary sponsor: Isala, Zwolle, the Netherlands.
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

Radiologic recurrence rate (CT-scan) of hiatal hernia.

Secondary outcome

- Development of post-operative dysphagia.

- Overall satisfaction with surgical outcome.

- Major complications

„X Postoperative hemorrhage with necessity for reoperation

„X Organ perforation (stomach, esophagus, small intestine, colon)

„X Major hemorrhage (>500cc) during operation

„X Lung or cardiac injury during operation

- Minor complications

„X Surgical site infection

„X Minor bleeding (<500cc) during operation

„X Postoperative pneumonia

„X Postoperative urinary tract infection

„X Postoperative deep venous thrombosis

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. Results of the PRIME trial, in which non-absorbable mesh reinforcement of the posterior cruroplasty was investigated, showed equal recurrence compared to primary repair after 6 months. It is hypothesized that circular absorbable MESH reinforcement of the hiatus could reduce recurrence rate.

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 (110 versus 110).

Study population: Adult patients with proven hiatus hernia type II-IV (defined by preoperative CT-scan).

Intervention: Patients will be randomized to undergo a laparoscopic primary crural repair with sutures alone or suture repair augmented with prosthetic absorbable, circular mesh at the hiatus.

Main study parameters/endpoints: Radiologic integrity of the hiatal repair is the main endpoint. Secondary objectives are clinical recurrence of the hernia, development of post-operative reflux disease, postoperative side effects and 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 CT scan 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 10 years. Patients will undergo similar to standard post-operative follow-up and including CT-scan at 3 months and 1 and 5 years after surgery.

Study objective

Bio-aborbable circular mesh reinforcement of the hiatus reduces recurrence rate after hiatal hernia repair.

Study design

3 months postoperatively

3 years postoperatively

Intervention

1. Laparoscopic primary hiatal hernia repair and 180 degrees fundoplication.

2. Laparoscopic primary hiatal repair with circular bio-absorbable mesh reinforcement and 180 degrees fundoplication.

Contacts

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Eligibility criteria

Inclusion criteria

- Age > 18 years

- Hiatus hernia type II-IV

- Laparoscopic surgical repair clinically indicated

- Fit for surgery

- Suitable for both procedures

Exclusion criteria

- Age < 18 years

- Hiatus hernia type I.

- No informed consent

- Previous anti-reflux surgery or repair for hiatus hernia

- Pregnancy

- 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:	Pending
Start date (anticipated):	01-01-2020
Enrollment:	220
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Ethics review

Positive opinion

Date:	21-05-2017
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 48062
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL6331
NTR-old	NTR6523
CCMO	NL69356.075.19
OMON	NL-OMON48062

Study results