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

Published: 01-10-2019
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To define the optimum laparoscopic hiatus hernia repair, ensuring long-term effect with minimal postoperative side effects.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Abdominal hernias and other abdominal wall conditions
Study type	Interventional

Summary

ID

NL-OMON48062

Source
ToetsingOnline

Brief title
PRIME-II trial

Condition

- Abdominal hernias and other abdominal wall conditions
- Gastrointestinal therapeutic procedures

Synonym
Diaphragmatic Hernia, Hiatal Hernia

Research involving
Human

Sponsors and support

Primary sponsor: Isala Klinieken
Source(s) of monetary or material Support: Geen financiering;het betreft een investigator driven studie waar geen funding voor is. ,W. L. Gore & Associates Inc, U.S.A.

Intervention

Keyword: Cruroplasty, Hiatal hernia, Laparoscopy, Mesh-repair

Outcome measures

Primary outcome

Radiologic integrity of the hiatal repair is the main endpoint.

Secondary outcome

Secondary objectives are clinical recurrence of the hernia, development of

post-operative reflux disease, postoperative side effects and satisfaction with

surgical outcome.

Study description

Background summary

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.

Study 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).

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.

Study burden and risks

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.

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

- 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:	Single blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	08-01-2020
Enrollment:	220
Type:	Actual

Medical products/devices used

Generic name:	Bio-A mesh
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	01-10-2019
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	28-02-2020
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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: 27270
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL69356.075.19