Recurrence rate of hiatal hernia repair with biomesh compared to repair without mesh * a double blinded, randomized, controlled trial.

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The above mentioned literature shows that repair of a hiatal hernia using a mesh gives fewer recurrences than repair without mesh. However, there are few prospective randomized controlled trials that provide clear results about this. The most...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Abdominal hernias and other abdominal wall conditions
Study type	Interventional

Summary

ID

NL-OMON36174

Source
ToetsingOnline

Brief title
Herbi 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: Atrium Medisch Centrum
Source(s) of monetary or material Support: Er is geen financiering nodig.

Intervention

Keyword: Biomesh, Hernia, Hiatal, Mesh

Outcome measures

Primary outcome

Recurrence rate (anatomical) in both intervention and control group

Percentage of mesh erosions in the intervention group

Percentage of mesh wrap migrations

Complaints of pain, reflux or dysphagia in both groups

Secondary outcome

Operative time

Length of hospital stay

Mesh infections

Wound infections

Gastrointestinal quality of life index (GIQLI)

Study description

Background summary

Repair of a hiatal hernia is a procedure with a high risk of recurrence. Based on the available literature it is concluded that recurrence rates are lower when a mesh is used. However, mesh use can cause serious complications such as mesh erosion which is why many surgeons still prefer crural closure with sutures. With this study we want to investigate if one of these techniques has a clear preference in terms of recurrence rates and complications.

There are many contradictions in the literature about using a mesh in the repair of a hiatal hernia. Recurrence rates up to 43% are reported for laparoscopic primary closed paraoesophageal hernias. For these operations wrap migration rates of up to 26% are reported.
A review of five case series, 6 retrospective reviews, 4 prospective randomized trials and 4 prospective nonrandomized trials showed a recurrence rate of 2.6% for repair using mesh and 15% without mesh. None of these articles reported an erosion of the mesh in the gastrointestinal tract.
Of the 986 patients in total who had a mesh in the review of Granderath et al. there was one patient with a esophageal stenosis, one patient with a mesh-induced esophageal scarification, one patient with an asymptomatic esophageal mesh erosion, one patient with a cardiac tamponade secondary to mesh fixation with tacks (resulting in death), one patient with hiatal fibrosis, 2 patients with hiatal fibrotic damage / esophageal mesh erosion and one patient with penetration of the cardiac lumen. These complications all occurred in patients with a synthetic mesh.

Study objective

The above mentioned literature shows that repair of a hiatal hernia using a mesh gives fewer recurrences than repair without mesh. However, there are few prospective randomized controlled trials that provide clear results about this.
The most serious complication of repair with mesh is mesh erosion and based on previous studies there seems to be a lower risk of erosion using a biomesh.

Study design

The study will be a multi-centre double-blinded Randomized Controlled Trial.
The trial is prospective in nature and data will be collected through a digital database.
50% of the participants in the intervention group will undergo repair of hiatal hernia through biomesh and the remaining 50% in the control group will receive a repair without mesh placement.

Intervention

Intervention:
Laparoscopic hernia repair with biomesh
Control group: Laparoscopic hernia repair without biomesh

Study burden and risks

The burden on patients for participating in this study is low. All included patients would also have surgery if they didn*t participate in the study. The extra burden is in filling in questionnaires.

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

Patients diagnosed with a diaphragmatic hernia
Patients older than 18 years
Patients under 75 years
ASA 1, 2 and 3

Exclusion criteria

Lack of informed consent
Recurrent diaphragmatic hernia
Previous upper abdominal surgery
Pregnancy

Immunocompromised patients
Use of steroids
ASA IV and higher

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO

Date:	19-07-2011
Application type:	First submission
Review commission:	METC Z: Zuyderland-Zuyd (Heerlen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL36573.096.11