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

Gepubliceerd: 03-01-2013 Laatst bijgewerkt: 15-05-2024

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

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23150

Bron
NTR

Verkorte titel
PRIME

Aandoening

Hiatus Hernia

Ondersteuning

Primaire sponsor: Antonius Ziekenhuis, Nieuwegein
Overige ondersteuning: Antonius Ziekenhuis, Nieuwegein

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Integrity of the hiatal repair is the main endpoint.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age ≥ 18 years;

2. Hiatus hernia;

3. Laparoscopic surgical repair clinically indicated;

4. Fit for surgery;

5. Suitable for both procedures.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Age < 18 years;

2. No informed consent;

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

4. Pregnancy.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-02-2013
Aantal proefpersonen:	72
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 39875
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

N/A