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

Gepubliceerd: 21-05-2017 Laatst bijgewerkt: 15-05-2024

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

| | |
|---|---|
| **Ethische beoordeling** | Positief advies |
| **Status** | Werving nog niet gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON27270

**Bron**
NTR

**Verkorte titel**
PRIME-II

**Aandoening**

Adults with giant hiatal hernia`s.

### Ondersteuning

**Primaire sponsor:** Isala, Zwolle, the Netherlands.
**Overige ondersteuning:** None

## Onderzoeksproduct en/of interventie

## Uitkomstmaten

### Primaire uitkomstmaten

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

# 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. 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.

### Doel van het onderzoek

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

**Onderzoeksopzet**

3 months postoperatively

3 years postoperatively

**Onderzoeksproduct en/of interventie**

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.

# Contactpersonen

## Publiek

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## Wetenschappelijk

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# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age > 18 years

- Hiatus hernia type II-IV

- Laparoscopic surgical repair clinically indicated

- Fit for surgery

- Suitable for both procedures

### Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Age < 18 years

- Hiatus hernia type I.

- No informed consent

- Previous anti-reflux surgery or repair for hiatus hernia

- Pregnancy

- Achalasia

## 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: | 01-01-2020 |
| Aantal proefpersonen: | 220 |

Type: Verwachte startdatum

### Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

**Wordt de data na het onderzoek gedeeld:** Ja

## Ethische beoordeling

Positief advies
Datum: 21-05-2017
Soort: Eerste indiening

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 48062
Bron: ToetsingOnline
Titel:

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

### In overige registers

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

## Resultaten