

# Mesh versus patch for hernia epigastrica and umbilical repair.

## A multicenter patient-blinded randomized trial.

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

### Summary

#### ID

NL-OMON39471

#### Source

ToetsingOnline

#### Brief title

MORHPEUS Mesh OR Patch for Hernia on Epigastric and Umbilical Sites

#### Condition

- Other condition

#### Synonym

Umbilical and epigastric hernia

#### Health condition

buikwandbreuken

#### Research involving

Human

## Sponsors and support

**Primary sponsor:** Catharina-ziekenhuis

**Source(s) of monetary or material Support:** Ministerie van OC&W, Johnson & Johnson

## Intervention

**Keyword:** Epigastric hernia, Mesh, Umbilical hernia, Ventral patch

## Outcome measures

### Primary outcome

Primary endpoint is number of complications.

A complication is defined as unexpected event related to the operation field which necessitates a treatment within 3 months postoperatively. Treatment can be initiated by primary as well as general physician. These includes

- peroperative bleeding or other damage
- prescribed medication such as antibiotics and analgesics after discharge other than paracetamol
- re-intervention for haematoma, abscess drainage, exploration due to pain / early recurrence / intra-abdominal problems
- woundcare at least the equivalent of rinsing once a day
- hospital stay longer than expected or re-admission for observation

### Secondary outcome

Pre-operative

Length, weight, Verbal Descriptor Scale (VDS) pain at rest, during exercise,

VDS cosmetics, intensity of daily activities/work

## Per-operative

Randomized device, incarceration, resection hernia sac, diameter hernia, enlargement hernia, closure of fascia, presence of adhesions, operation duration, VDS ease procedure, complications, reason for protocol deviations

## Postoperative

Complications, Verbal Descriptor Scale (VDS) pain at rest, during exercise, VDS cosmetics, recurrence,

## Costs

Post-hoc computing based on number of visits, operation duration, device and complications related costs up to 2 years postoperatively.

# Study description

## Background summary

There is a tendency for the use of mesh in epigastric and umbilical hernia repair as it is standard in the repair of other hernias. Mesh-based repair reduces the recurrence rate of approximately 15-20% down to 3-10%. Whether or not this also accounts for small hernias is unknown. A currently conducted HUMP-trial will provide this information for specifically umbilical hernia less than 2 cm's. A possible reason for still suturing small hernia could be the challenge placing a mesh in the pre-peritoneal space.

A mesh, designed for this use, can be placed intra-peritoneally. An approach is laparoscopically which includes new openings in the fascia. This probably has induced the innovation of so-called patches. A patch is a mesh which can be introduced open and pulled back against the abdominal wall.

Theoretically, these patches are specially useful for small hernias as less dissection is required. Its feasibility has been reported before, however, it remains unclear this ease is associated with less complications. A surgeon may

favour a less complicated procedure, this however not a clinically important parameter. Identifying a best procedure not only has consequences for around 4100 umbilical and 2400 epigastric hernias in The Netherlands, also for frequently encountered incisional hernia such as on previous trocar sites.

## **Study objective**

Primary objective is the evaluation a ventral patch is associated with less complications than a conventional mesh for epigastric and umbilical hernias. Complications are defined as unexpected events necessitating a treatment within the period of three months postoperatively. Secondary endpoints are pain, cosmetics, operation duration and costs.

## **Study design**

Design = patient-blinded randomized trial

Type = superiority study

Setting = national multicenter trial

## **Intervention**

All procedures will be performed under general anesthesia. Addition of local anestheticum is advocated. Prophylactic antibiotics only on indication. Use of drapes or drains is not advocated. Enlarging hernia and closure of fascia over mesh is allowed.

Conventional repair: incision para-umbilical or at epigastric site. Dissection subcutaneously to fascia. Mobilising hernia sac. Opening for inspection is allowed. Reposition of sac. Dissection pre-peritoneally space. Placing polypropylene mesh, minimum size 6 cm's. Fixation with non-absorbable sutures.

Patch repair; opening hernia sac, ensuring no adhesions at peritoneum. Placing patch against abdominal wall. Fixation to fascia. Standard mesh is PROCEED tm VENTRAL PATCH (Ethicon, Norderstedt, Germany).

## **Study burden and risks**

Risks are similar to daily practice

Extent of burden is 1 hour for fulfilling questionnaires within study time of 2 years

## **Contacts**

### **Public**

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NL

## Trial sites

### Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- single primary umbilical or epigastric hernia
- size less than 3 cm (2 fingers)

### Exclusion criteria

- age < 18 years
- not capable to understand and complete questionnaires

## 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:	Recruitment stopped
Start date (anticipated):	03-01-2011
Enrollment:	346
Type:	Actual

## Medical products/devices used

Generic name:	Proceed Ventral Patch
Registration:	Yes - CE intended use

## Ethics review

Approved WMO	
Date:	18-11-2010
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	
Date:	30-11-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	
Date:	20-12-2011
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United

(Nieuwegein)

Approved WMO

Date: 02-10-2012

Application type: Amendment

Review commission: MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date: 24-01-2013

Application type: Amendment

Review commission: MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date: 27-03-2013

Application type: Amendment

Review commission: MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date: 25-09-2013

Application type: Amendment

Review commission: MEC-U: Medical Research Ethics Committees United (Nieuwegein)

## 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**

CCMO

**ID**

NL33995.060.10