Mesh versus patch for hernia epigastrica and umbilical repair. A multicenter patient-blinded randomized trial.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	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 postoperatievly. Treatment can

be initiated by primar 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, abccess 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, weigth, Verbal Descriptor Scale (VDS) pain at rest, during excercise,

VDS cosmetics, intensity of daily activities/work

Per-operative

Randomized device, incarceration, resection hernia sac, diameter hernia,

enlargment 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 excercise,

VDS cosmetics, recurrence,

Costs

Post-hoc computing based on number of vistis, 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 apporach is laparoscopically which includes new openings in the fascia.
This probably has induced the innovation of so-called patches. A patch is a mesh whch can be introduced open and pulled back against the abdominal wall.

Theoratically, these patches are specially useful for small hernias as less dissection is required. Its feasability 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 obejective is the evaluation a ventral patch is associtaed 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 lokal anestheticum is advocated. Profylactic 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 subcutanously 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-absorbabale sutures.

Patch repair; opening hernia sac, ensuring no adhesions at peritoneum. Placing patch against abdominal waal. 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

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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	ID
CCMO	NL33995.060.10