A Post-Market, Prospective, Multi-Center, Single-Arm Clinical Investigation of Phasix Mesh for VHWG Grade 3 Midline Hernia Repair

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The objective of this study is to collect additional data on safety and performance of Phasix* Mesh in subjects requiring VHWG Grade 3 midline hernia repair.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Soft tissue therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON46922

Source
ToetsingOnline

Brief title
Phasix mesh for the treatment of VHWG Grade 3 Midline Hernia Repair

Condition

- Soft tissue therapeutic procedures

Synonym
hernia cicatricalis, Incisional hernia, ventral hernia

Research involving
Human

Sponsors and support

Primary sponsor: Davol Inc.
Source(s) of monetary or material Support: Davol Inc.

Intervention

Keyword: Midline abdominal repair, Phasix Mesh, Prospective study, Ventral/incisional Hernia

Outcome measures

Primary outcome

Surgical Site Occurrence (SSO) rate up to and including, the 3-month (± 14 days) follow-up assessment.

Occurrences at the surgical site will be assessed by physical examination at each study visit through 3 months (± 14 days). Surgical site occurrence will be defined as hematoma, seroma, surgical site infection, wound dehiscence, skin necrosis and fistula requiring intervention.

Secondary outcome

1. Surgical Site Occurrence (SSO) rate > 3-month follow-up assessment
2. Hernia Recurrence Rate (via physical exam, if uncertain via ultrasonography, if uncertain, via CT/MRI)
3. Surgical Site Infection rate (see 18.1)
4. Pain - Visual Analog Scale (VAS)
5. Device related adverse event incidence
6. Rate of reoperation due to the index hernia repair
7. Quality of life assessments (Carolinas Comfort Scale® and EQ-5D*)
8. Surgical procedure time as measured from incision to closure (skin to skin)
9. Return to work
10. Length of hospital stay (day of index surgery until day of discharge, LOS)

Study description

Background summary

Incisional hernia is one of the most common complications after laparotomy. The incidence is 10 to 20%. In general, mesh repair is required for treatment of incisional hernia. The aim of surgical treatment of incisional hernias is to relieve symptoms (pain and discomfort), to prevent complications (strangulation, respiratory dysfunction, or skin problems), or to resolve acute complications (incarceration, perforation and strangulation).

There are several options for mesh repair, such as the use of synthetic or biological meshes. However, there is no clear-cut consensus regarding the optimal hernia repair technique in complex hernia repair cases, where patient co-morbidities exist and a high risk of infection is present. The *standard mesh*, which is a synthetic mesh, is strong and reduces the risk of recurrences. However, these non-resorbable synthetic meshes carry the risk of infection, pain, adhesions, fistulae and foreign body reaction in complex hernia cases. Currently, the Ventral Hernia Working Group (VHWG) does not have a standard treatment for Grade 3 midline hernia patients.

Placement of a resorbable biological mesh could be the standard treatment, but this type of mesh is not used by most centres. Currently, there is no evidence that the biological mesh is strong enough, and there is no evidence that it does not resorb too quickly. In addition, the biologic mesh is too expensive for most centres. Furthermore, a biological mesh is made of porcine dermis and is thus xenogeneic tissue. The treatment with biologics is not validated by randomized or prospective cohort studies.

The consequence of the fact that there is not yet a standard treatment for this patient group, is that an untreated (or not optimal treated) patient group is being maintained. This is unacceptable.

Thus, the ideal resorbable mesh should provide adequate structural support throughout the healing process and at the same time it should be fully resorbed when the wound has completely healed, thereby potentially reducing the chances for complications associated with the persistence of non-resorbable mesh material. The Phasix* mesh, which is a resorbable synthetic mesh, does not have the disadvantages of the biological mesh, is strong and does resorb slowly.

This study is being conducted to evaluate the use of Phasix* Mesh in incisional midline hernia repair in Ventral Hernia Working Group (VHWG) Grade 3 patients. All treated subjects will be followed for 24 months post-implantation.

Study objective

The objective of this study is to collect additional data on safety and performance of Phasix* Mesh in subjects requiring VHWG Grade 3 midline hernia repair.

Study design

This study will be a prospective multicenter cohort study.

Approximately 85 subjects, at approximately 12 sites will be enrolled and treated to study the use of Phasix* Mesh. All treated subjects will be followed for 2 years post-implantation. Follow-up visits will be conducted at Drain Removal per standard of care (SOC), 1, 3, 6, 12, 18 and 24 months following implantation. See Section 6 for a detailed schedule of study visits and procedures.

Follow up of the patients will take place at the outpatient clinic. Physical examination will be conducted, and patients will be asked to fill in the EQ-5D, VAS and Carolina Comfort Scale (except at drain removal visit).

Intervention

All subjects will undergo an open ventral repair of hernias. The size of the hernia is an intraoperative inclusion criterion and must be greater than 10 cm2. All other intraoperative exclusion criteria should be verified (e.g., absence of an active infection; presence of peritonitis; requirement of a hernia bridge as the sole repair procedure). Defect closure must be confirmed.

The surgical technique will require retro-rectus (onlay is allowed as an exception when retro-rectus placement cannot be achieved), using resorbable suture, with or without Component Separation Technique (CST). Subjects will be administered antibiotics according to hospital protocol. Subjects will be prepared to undergo hernia repair with Phasix Mesh following the instructions supplied by the manufacturer.

Phasix* Mesh will be placed in the retro-rectus space with resorbable sutures. The peritoneum should remain posterior to the mesh upon completion of mesh placement. Mesh may be cut to shape or size desired for each specific application. To prevent recurrence when repairing hernias, a mesh larger than the defect is required to ensure adequate coverage. The mesh is to be positioned so its edges extend beyond the margins of the defect by at least 5 cm. It is recommended that fixation be placed at approximately 5 to 6 cm intervals (6 to 12 resorbable sutures) around the periphery of the mesh. The edges are then fixated to assure proper closure under correct tension.

The procedure may include CST to obtain site closure. All incisions will be closed with staples and/or sutures and wounds will be dressed with sterile

occlusive dressings.

The following information will be collected in the eCRF:
*- Intra-operative evaluation of surgical site and abdomen
*- Intra operative assessment and description of hernia
*- Intraoperative assessment of complications e.g. enterotomy
*- Surgical procedure
*- Mesh details
*- Fixation details
*- Pre- and post-operative wound assessment: signs of infection, status and location of potential previous mesh, signs of necrosis
*- Wound closure
*- Adverse Events
*- Device failure/ malfunction/ defects

Study burden and risks

During follow up, patients will have to visit the outpatient clinic several times (month 1, 3, 6 12, 18, 24), where they will be physically examined. Furthermore, they will have to fill in QoL 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

The subject must meet all of the criteria listed below to be enrolled in the study:
1. Subject must be 18 years of age or older.
2. Subject must be diagnosed with incisional midline hernia.
3. Subject has a VHWG Grade 3 hernia (as defined in 5.2.3).
4. Size of hernia * 10 cm2.
5. Subject must be willing to undergo a planned retro-rectus hernia repair (onlay allowed as an exception when retro-rectus placement cannot be achieved; using absorbable suture) with or without Component Separation Technique (CST).
6. The subject is legally competent, has been informed of the nature, the scope and the relevance of the study, voluntarily agrees to participation and the study*s provisions, and has duly signed the informed consent form (ICF). Subject agrees to comply with the protocol-mandated procedures and visits.

Exclusion criteria

The subject must be excluded from study enrollment if any of the following criteria are met:
1. Subject with > 4 previous repairs of the hernia under observation.
2. Body Mass Index (BMI) > 35 kg/m2.
3. The subject is on, or suspected to be placed on, chemotherapy medications during any part of the study.
4. The subject has peritonitis.
5. Known human immunodeficiency virus (HIV) infection (if documented in the subject*s record).
6. The subject has cirrhosis of the liver and/or ascites.
7. Subject is American Society of Anesthesiology Class 4 or 5.
8. Complete removal of existing mesh from a prior hernia repair (in the same affected area) is not possible.
9. The hernia repair requires more than a single piece mesh (with adequate overlap beyond the margins of the defect on all sides).
10. Subject has intact permanent mesh adjacent to the current hernia to be repaired.
11. Subject*s hernia repair requires intraabdominal mesh placement.
12. Surgical technique requires surgical bridge repair as the sole repair.
13. Subject has any condition that, in the opinion of the Investigator, would preclude the use of the study device, or preclude the subject from completing the follow-up requirements.
14. Subject is pregnant or has plans to become pregnant during the study period or is

currently breastfeeding.
15. Subject has an alcohol/substance abuse problem or has had a relapse within 12 months of the screening visit.
16. Subject was involved in another interventional clinical study in the last 30 days prior to ICF signature.
17. Subject is part of the site personnel directly involved with this study.
18. Subject has a life expectancy of less than 2 years at the time of enrollment.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-08-2016
Enrollment:	18
Type:	Actual

Ethics review

Approved WMO Date:	12-07-2016
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	16-11-2016
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO

Date:	12-12-2018
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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
ClinicalTrials.gov	NCT02720042
CCMO	NL55094.078.15

Study results

Date completed:	20-06-2019
Actual enrolment:	14

Summary results
Trial is onging in other countries