MARS study- Mesh Augmented Reinforcement of Abdominal Wall Suture Line in Patients Undergoing Midline Laparotomy to limit the Rate of Incisional Hernia (IH) Occurrence

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The purpose of this prospective, pivotal, multi-center, single-arm cohort, pre-market, investigational clinical study is to assess the safety and performance of Deternia* Self-Gripping Resorbable Mesh when used for suture line reinforcement after...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Abdominal hernias and other abdominal wall conditions
Study type	Interventional

Summary

ID

NL-OMON53544

Source
ToetsingOnline

Brief title
MARS study

Condition

- Abdominal hernias and other abdominal wall conditions

Synonym
Incisional Hernia, Midline Laparotomy

Research involving
Human

Sponsors and support

Primary sponsor: Sofradim Production S.A.S.U, a Medtronic plc company
Source(s) of monetary or material Support: Medtronic

Intervention

Keyword: Incisional Hernia (IH), Midline Laparotomy, Self-Gripping Resorable Mesh

Outcome measures

Primary outcome

Incidence of IH at 12-month post-operative visit evaluated clinically and by imagery by means of ultrasonography. (In case of discrepancy, imagery will be decisive, see Appendix D). If there is a suspicion of hernia based on clinical evaluation, but the ultrasound examination is negative, Computerized Tomography-Scan (CT scan) may be performed according to site standard of care.

Secondary outcome

Secondary Endpoints include,

* Incidence of IH at 24-, and 36-months follow-up assessed by imaging (Ultrasound) and physical examination. (In case of discrepancy, imagery will be decisive.)

* Incidence of clinical (physical examination) IH at 3-, 6-, 12-, 24- and 36-months follow-up assessed by physical examination.

*Time to IH (from surgery time-point)

* Time to other adverse device effects (ADE) occurrence (from skin incision time-point)

* Incidence of all ADEs (adverse event related to the mesh and/or mesh-augmented reinforcement procedure) intra-operatively, at discharge, within

3-, 6-, 12-, 24-, and 36- months following the use of Deternia* Self-Gripping Resorbable Mesh

* Incidence of adverse events of interest (symptomatic seroma requiring action taken, hematoma needing surgical revision, surgical site infection (SSI) defined via the CDC classification of SSI (superficial, deep or organ space), wound dehiscence (skin and/or fascial), mesh removal) intra-operatively, at discharge, within 3-, 6-, 12-, 24-, and 36-months following the use of Deternia* Self-Gripping Resorbable Mesh

*Pain at the site of surgery evaluated with Numeric Rating Scale (NRS) score from 0 to 10 at baseline (screening), discharge and at 3-, 6-, 12-, 24-, and 36- months post-operative visits, and change from baseline to follow-up visits

* EQ-5D-5L quality of life (QoL) at baseline, 3-, 6-, 12-, 24- and 36-month post-operative visit, and change from baseline to follow-up visits

* Surgeon satisfaction questionnaire post-operative on Day 0

* Hospital length of stay (inpatient)

* Readmission and reoperation rate related to Mesh device and/or Mesh Augmented Reinforcement procedure.

Study description

Background summary

Pls see section 4.1 of the CIP version 2.0, 10Jul2023

Study objective

The purpose of this prospective, pivotal, multi-center, single-arm cohort, pre-market, investigational clinical study is to assess the safety and

performance of Deternia* Self-Gripping Resorbable Mesh when used for suture line reinforcement after midline laparotomy in clean and clean-contaminated fields (CDC Classification I and II). Data from this study will be used to support market applications.

Study design

This study is a prospective, pivotal, multi-center, single-arm, pre-market, investigational clinical study evaluating the use of the Deternia* Self-Gripping Resorbable Mesh in patients undergoing midline laparotomy in clean and clean-contaminated fields (CDC Classification I and II) in order to limit the rate of IH occurrence.
All subjects will receive midline abdominal wall closure with small bites technique reinforced by Deternia* Self-Gripping Resorbable Mesh placed in the retrorectus space. The purpose of the investigation is to limit the IH occurrence and demonstrate expected performance of the study device against a Performance Goal based on historical data on primary laparotomy incision suture closure with small bites only.

Study duration is estimated to be 27 months of recruitment and 36 months of follow-up post-surgery.
Participating centers and investigators are qualified surgeons experienced in the surgical management of patients with mesh augmented reinforcement for abdominal laparotomies or experienced with mesh placement for hernia repair.

Intervention

Subjects will be evaluated at baseline/screening, during surgery, at discharge, and at 3-, 6-, 12-, 24-, and 36-months post-surgery. Assessments to be conducted/data collected include:

Pre-operative data:
* Subject eligibility (pre-operative criteria)
* Subject informed consent (Subject should be re-consented if date of original consent is greater than 30 days before the procedure)
* Subject demographics
* BMI
* Medical and abdominal surgical histories and relevant risk factors
* American Society of Anesthesiologists (ASA) grade
* EQ-5D-5L Quality of life questionnaire - pre-operative assessment
* Pain (Numeric Rating Scale (NRS) score from 0 to 10) of the abdominal wall
Note: Preoperative (screening) day and operative day can be combined

Operative data (Day 0):
* Eligibility criteria (Intra-operative criteria)
* Pregnancy status

* BMI
* Date of surgery, operative start and stop times (from skin incision to skin closure)
* General anesthesia information (type)
* Intraoperative wound contamination class
* Antibiotic prophylaxis
* Anticoagulation use
* Indication for midline laparotomy, surgical technique approach, and type of surgery
* Abdomen description and fascial closure details (length of fascial incision, suturing closure technique, suture type, suture length, drains left)
* Study device data (mesh size, location of mesh placement, mesh overlap, location of grip placement, lot number)
* Number/type of fixation, if applicable
* Adverse events and device deficiencies, if applicable,
* Surgeon satisfaction questionnaire
* Amount of time to create the retrorectus space and insert, position, and fixate the mesh, if applicable
Note: Preoperative (Screening) Day and Operative Day can be combined

Discharge data:
* Pain (Numeric Rating Scale (NRS) score from 0 to 10) at site of surgery
* Adverse events and device deficiencies, if applicable
* Anticoagulation use, if applicable
* Length of hospital stay

3-month (± 14 days) and 6-month (± 14 days) Follow-up:
* Pain (NRS score from 0 to 10) at site of surgery
* EQ-5D-5L Quality of Life questionnaire - Post-operative assessment
* Adverse events and device deficiencies, if applicable
* Anticoagulation use, if applicable
* Clinical physical examination for incisional hernia
* Details of incisional hernia, if applicable (EHS classification, mesh placement location, defect size, etc.)
* Mesh removal, if applicable

12-month (± 30 Days), 24-month (± 45 Days), and 36-month (± 45 Days) Follow-up:
* Pain (NRS score from 0 to 10) at site of surgery
* EQ-5D-5L Quality of Life questionnaire - Post-operative assessment
* Adverse events and device deficiencies, if applicable
* Anticoagulation use, if applicable
* Clinical physical examination for incisional hernia
* Details of incisional hernia if applicable (EHS classification, mesh placement location, defect size, etc.)
* Imagery (ultrasound required and CT scan as desired/needed per SOC) for incisional hernia
* Mesh removal, if applicable

Additional visits
* Clinical physical examination for incisional hernia if applicable
* Details of incisional hernia, if applicable (EHS classification, mesh placement location, defect size, etc.)
* Imagery (ultrasound required and CT scan as desired/needed per SOC/) for incisional hernia if applicable
* Mesh removal, if applicable
* Adverse events and device deficiencies, if applicable
* Anticoagulation use, if applicable

Study burden and risks

Based on the literature, there are 3 type of prosthetic materials mostly used for the prevention of incisional hernia including:

•Synthetic nonabsorbable or partially absorbable material: will remain in the body indefinitely and is considered a permanent implantation; used to provide permanent reinforcement to the abdominal wall
•Biological material: "transforms" itself into the tissue with which it comes in contact and disappears completely after having exercised its containment effect for the necessary time
•Biosynthetic or synthetic fully and slow absorbable material: constitutes a class of materials that are completely absorbed by the surrounding tissue over time

According to the available clinical data, there is quantity of evidence on the use of permanent synthetic mesh as prophylactic mesh for prevention of incisional hernia. However, some surgeons might be mostly reluctant to implant a permanent synthetic mesh leaving permanent foreign body material in a patient because of the long-term postoperative complications such as infection and chronic pain. Biologic mesh are also used in this indication but their high costs limit their use and do not have always optimal properties for this purpose (references: Soderback, Pizza, Faulkner).

Deternia* Self Gripping Resorbable mesh is a synthetic slowly resorbable mesh that will reinforce the abdominal wall during the critical healing period and progressively resorbs while fascia will retrieve its original strength over the time. There is therefore medical-scientific interest in examining if such mesh will result in the same outcomes as synthetic permanent mesh with fewer long-term side effects.
Regarding the risk/benefit assessment of a slowly resorbable type of mesh used in this study, Medtronic has performed a literature review of the available clinical data. The 3 on-market products considered to be competitive to Deternia* Self-Gripping Resorbable mesh are: Phasix* (Bard), Gore* Bio A* (Gore), and Tiger* Matrix (Novus Scientific). Please refer to Section 4.1. Previous Clinical Experience in chapter 4. Existing Clinical Data in the MARS Investigator*s Brochure v.1.0-21Apr2022 for more information.

This literature review concluded that based on clinical data from published scientific literature and post market surveillance, synthetic absorbable meshes, which are part of the state of the art for suture-line reinforcement, appear to present a favorable benefit/risk profile in such an indication. The benefit/risk assessment performed for the study mesh is also described in Section 5.1. Benefit-Risk Analysis and Results under chapter 5. Risk Management of the Investigational Device in the MARS Investigator*s Brochure v.1.0 - 21Apr2022 and in the Risk Management Report RMR070 Rev. B .

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Preoperative Inclusion Criteria
1. Subject has provided informed consent.

2. Subject is >=18 years of age at the time of consent.
3. Subject will be undergoing an elective surgery with a planned midline laparotomy with retrorectus mesh placement.
3A. Subject will be undergoing an elective laparoscopy with a planned possibility of a conversion to midline laparotomy or an elective laparoscopy with a planned possible midline laparotomy for specimen extraction.

Exclusion criteria

Preoperative Exclusion Criteria
1. Subject is undergoing emergency surgery, i.e. lifesaving procedures performed where patient is in imminent danger of death
2. Subject has a history of allergic reactions after application of poly-L-lactide, poly-trimethylene carbonate copolymers (PLLA/TMC)
3. Subject is pregnant or is planning pregnancy during study duration period(Females of child-bearing potential will be required to provide either a urine or serum pregnancy test (except for subjects who are surgically sterile or are at least 2 years post-menopausal))
3a: Subject is breastfeeding or is planning to breastfeed during the study duration period
4. Subject is unable or unwilling to comply with the study requirements or follow-up schedule
5. Subject is scheduled for another planned surgery, and subsequent surgery would jeopardize previous application of study treatment
6. Subject with a body mass index (BMI) > 45 kg/m2
7. Subjects with the following medical interventions/medical conditions are excluded from participation in the study: uncontrolled diabetes (hemoglobin A1c (Hb1Ac) > 60mmol/mol), cirrhosis, stoma wearers
8. Concomitant ostomy (stomacreation)
9. Subject who had received a mesh in a previous ventral hernia repair or has an existing ventral hernia>2cm
10. Subject with a life expectancy inferior to the study follow-up duration (36 months)
11. Study procedure is a relaparotomy within 30 days of previous abdominal surgery
12. Subject with an American Society of Anesthesiologists (ASA) scores higher than 3
13. Subject has participated in an investigational drug study within the washout period of the drug or in a device study that would interfere with mesh implantation or assessment of incisional hernia
14. Subject with current chemo and/or radiation therapy within 2 weeks of procedure
Only exclusion of chemotherapeutic drugs that have:
• Cytotoxic effect and/or
• Inhibit of cell replication and/or

• Impaired tissue healing
15. Subject with any history of ascites
16. Subject has a medical condition that precludes the patient from participation in the opinion of the investigator
17. Subject is undergoing a vascular procedure other than abdominal aortic aneurysm (AAA) surgery (i.e, only AAA surgeries accepted)

Intraoperative Exclusion criteria
1. Subject*s study procedure is in a contaminated or infected site as assessed by the Investigator(s) (CDC Class 3 and 4)
2. Abdomen is left open at the end of the procedure
3. Subject has an unsuspected ventral hernia >2cm encountered at the time of laparotomy
4. Inability to close the anterior fascia or keep the mesh securely out of the peritoneal cavity
5. Second-look procedure planned
6. Cases requiring a full-thickness partial resection of the abdominal wall (in particular the midline) because of involvement in neoplastic process or complex fistula
7. Inoperable tumor/poor prognostic cancer/patient non curatively treated
8. Subject has a suture length to wound length ratio< 3.5/1
9. Subject has any ongoing infection at the time of the surgery, that is uncontrolled and/or requiring treatment such as antibiotics
10. Subject was not implanted with Deternia* Self Gripping Resorbable Mesh
11. Subject requires more than 1 mesh

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	30-10-2023
Enrollment:	60

Type:	Actual

Medical products/devices used

Generic name:	Deternia Self-Gripping Resorbable Mesh
Registration:	No

Ethics review

Approved WMO Date:	03-02-2023
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	04-09-2023
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NCT05424484
CCMO	NL81131.000.22