Prevention of incisional hernia in high-risk patients with prophylactic slowly-resorbable TIGR® Matrix mesh (Novus Scientific, Uppsala Sweden) in midline laparotomies, a pilot study

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The objective of this study is to collect additional data on the performance and safety of the slowly-resorbable TIGR® mesh of incisional hernia prevention in patients with AAA undergoing midline laparotomy.

Ethical review	Not approved
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON56842

Source
ToetsingOnline

Brief title
PROTECT pilot study

Condition

- Other condition

Synonym
Incisional hernia

Health condition

Chirurgische aandoening: Littekenbreuken, preventief

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Novus Scientific AB

Intervention

Keyword: Incisional hernia, Mesh, Midline laparotomy, Resorbable

Outcome measures

Primary outcome

The primary endpoint is safety in terms of intra-operative and postoperative complications. Intra-operatively the feasibility of the product in this setting will be assessed, the time of implantation of the mesh will be recorded, any problems encountered by the researcher after each procedure will be asked. Post-operative complications including surgical site occurrence (SSO) according to the Ventral Hernia Working Group (surgical site infection (SSI), seroma, wound dehiscence, enterocutaneous fistula, wound cellulitis, non-healing incisional wound, fascial disruption, skin or soft tissue ischemia, skin or soft tissue necrosis, wound serous or purulent drainage, stitch absess, seroma, hematoma and infected or exposed mesh), SSOs requiring a procedural intervention (SSOPI) defined as wound opening or debridement, suture excision, percutaneous drainage, or mesh removal. Other post-operative complications compromise pulmonary infections and ventilation problems.

Secondary outcome

The secondary endpoints compromise the presence of incisional hernia as determined by physical examination or ultrasonography. Size (length, width,

diameter in cm) and location of the incisional hernia will be recorded. Location will be recorded relative to the abdomen (peri-umbilical, infra-umbilical, supra-umbilical, or lateral), and relative to the mesh (edge of the mesh, outside of the mesh covered area, or within the mesh covered area). Incisional hernia is defined as any abdominal wall gap with or without bulge in the area of a postoperative scar perceptible or palpable by clinical examination or imaging, as determined by Korenkov et al. and accepted by the European Hernia Society. An incisional hernia is defined as *symptomatic* if the hernia causes pain, discomfort, incarceration, or cosmetic complaints. Post-operative pain (VAS score) and quality of life (MOS SF-36, EQ-5D questionnaires and Carolinas Comfort Scale) will be obtained. During follow-up visits sensitivity of the skin in the area of the mesh placement will be assessed.

Study description

Background summary

Incisional hernia is one of the most frequent long-term complications after midline surgery, especially in high-risk groups such as patients with an abdominal aortic aneurysm (AAA). To prevent incisional hernias and potentially subsequent complications as strangulation and incarceration a prophylactic mesh can be placed. Usually a non-resorbable mesh is used. However, the advantage of a resorbable mesh is that the foreign material persisting in the patient is reduced, without compromising on the initial biomechanical resistance of the mesh. Therefore, this study will examine the effectiveness of synthetic, slowly-resorbable TIGR® Matrix mesh in preventing incisional hernias after laparotomy in patients with AAA.

Study objective

The objective of this study is to collect additional data on the performance

and safety of the slowly-resorbable TIGR® mesh of incisional hernia prevention in patients with AAA undergoing midline laparotomy.

Study design

This will be a prospective, multicenter, single-arm pilot study.
Patients with an AAA undergoing an elective midline laparotomy will receive closure of the fascia with the aid of a prosthetic mesh. Patients will receive prophylactic mesh augmentation with synthetic, slowly-resorbable TIGR® Matrix mesh in onlay position. Patients will visit the outpatient clinic at specific time points during three years of follow-up. The visit will be managed by a member of the study team, i.e. researcher, surgical resident or surgeon.

Intervention

An elective laparotomy through a midline incision will be performed. The operating vascular surgeon will close the abdomen wall as described below: First, the midline fascia will be closed with a running suture USP 2-0 PDS Plus II (Ethicon, Somerville, NJ, USA) with *small bites* technique. With this *small bites* technique the laparotomy wound is closed with a single layer aponeurotic suturing technique taking tissue bites of 5 mm and intersuture spacing of 5 mm. The ratio of suture length to wound length will be 4:1. Subsequently, the TIGR Matrix mesh will be placed in onlay position. Therefore, an anterior plane with a width of about 8 cm will be created between anterior rectus fascia and subcutis.

The surgeon will use the 20 cm by 30 cm sized TIGR® Matrix mesh and adjust this to a 6 cm by 30 cm mesh. The 6 cm by 30 cm TIGR® Matrix mesh will be placed on the anterior rectus fascia with a bilateral overlap of 3 cm. In case of an incision longer than 30 cm, two meshes will be tied to each other to obtain an overlap of 3 cm. To prevent migration of the mesh and to maintain good contact between the tissue and the mesh, the surgeon will fixate the mesh with USP 3-0 PDS Plus II (Ethicon, Somerville, NJ, USA) with intersuture spacing of 3 cm to the abdominal wall. The subcutaneous tissue and skin will be closed with sutures preferred by the surgeon (standard care).

Study burden and risks

The risk related to the procedure (closure of the abdominal wall with prophylactic resorbable TIGR® Matrix mesh placement in onlay position) are blood loss, hematoma, seroma, infection and pain. These risks are not directly related to the product (TIGR® Matrix mesh).

The potential benefits of this fully resorbable mesh compared to the non-resorbable meshes are a possible reduced risk of seroma formation, infection and persistent pain, however preserving a minimal risk of wound

dehiscence and incisional hernia.
No potential risks are known to be related to the use of this product.

Included patients will visit the outpatient clinic for five times during follow up. During the visit to the outpatient clinic, the surgical site will be assessed for incisional hernia, wound infection, seroma formation and other wound problems. In three of the five visits an ultrasound of the mideline scar will be performed. Also the patients will fill in two questionnaires (MOS SF-36, VAS, CCS, EQ-5D questionnaires) three times during the study.

No laboratory tests will be performed.

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

- Elective midline laparotomy for patients with Abdominal Aortic Aneurysm.
- Age >= 18 years.
- Signed informed consent by patient.

Exclusion criteria

- Pregnancy.
- Emergency procedures.
- Inclusion in other trials with interference of the primary endpoint.
- Life expectancy less than 24 months (as estimated by the attending physician).
- Immune suppression therapy within 2 weeks before surgery.

Study design

Design

Study type: Interventional

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	70
Type:	Anticipated

Medical products/devices used

Generic name:	TIGR Matrix slowly-resorbable mesh
Registration:	Yes - CE intended use

Ethics review

Not approved

Date:	16-04-2021
Application type:	First submission
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

ID: 22803
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL70332.078.19
Other	NL7909