Prevention of incisional hernia in high-risk patients with prophylactic slowly-resorbable TIGR® Matrix mesh in midline laparotomies.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON22803

Source
Nationaal Trial Register

Brief title
PROTECT

Health condition

Prevention of incisional hernia in high-risk patients

Sponsors and support

Primary sponsor: Novus Scientific AB, Uppsala Sweden
Source(s) of monetary or material Support: Novus Scientific AB, Uppsala Sweden

Intervention

Outcome measures

Primary outcome

The primary objective is to examine the effectiveness of incisional hernia prevention with

synthetic, slowly-resorbable TIGR® Matrix mesh placement in patients with AAA undergoing midline laparotomy.

Secondary outcome

The secondary objectives are to measure relevant postoperative complications, postoperative pain, sensitivity of the skin in the area of the mesh placement and quality of life.

Study description

Background summary

Rationale: 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.
Objective: The primary objective is to examine the effectiveness of synthetic, slowly resorbable TIGR® Matrix mesh in preventing incisional hernias in patients with AAA that undergo midline laparotomy.
Study design: Prospective, multicenter, single-arm trial.
Study population: Patients of 18 years or older, with AAA undergoing an elective midline laparotomy.
Intervention: During closure of the abdominal wall, TIGR® Matrix Mesh will be placed in onlay position to prevent incisional hernia.
Main study parameters/endpoints: The primary endpoint is the presence of incisional hernia after 3 years of follow-up.
Nature and extent of the burden and risks associated with participation, benefit and group relatedness: 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, while preserving a reduced risk of wound dehiscence and incisional hernia.

Study objective

Reinforcement with prophylactic slowly-resorbable TIGR Matrix mesh in high-risk patients undergoing midline laparotomy is effective.

Study design

30 days, 3 months, 1 year, 2 years and 3 years

Intervention

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.

Contacts

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Eligibility criteria

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
Intervention model:	Other
Allocation:	Non controlled trial

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2019
Enrollment:	70
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 56842
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL7909
CCMO	NL70332.078.19
OMON	NL-OMON56842

Study results