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

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

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22803

Bron
Nationaal Trial Register

Verkorte titel
PROTECT

Aandoening

Prevention of incisional hernia in high-risk patients

Ondersteuning

Primaire sponsor: Novus Scientific AB, Uppsala Sweden
Overige ondersteuning: Novus Scientific AB, Uppsala Sweden

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-10-2019
Aantal proefpersonen:	70
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 56842
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten