SloWly-resorbable TIGR® Matrix mesh For totally extraperitoneal (TEP) endoscopic reinforcemenT of inguinal-related groin pain, a pilot study

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Totally extraperitoneal endoscopic reinforcement with slowly-resorbable TIGR Matrix mesh in patients with inguinal-related groin pain is effective.

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

Samenvatting

ID

NL-OMON22732

Bron
Nationaal Trial Register

Verkorte titel
SWIFT

Aandoening

Inguinal-related groin pain

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 of current pilot study is evaluate safety in terms of mesh related complications

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Inguinal-related groin pain is a frequent complaint among athletes. Surgical treatment options include endoscopic totally extraperitoneal (TEP) procedure with mesh. The most frequently used method for surgical treatment is with non-resorbable synthetic mesh. Slowly-resorbable synthetic mesh offers possible advantages over non-resorbable synthetic mesh in the form of a lower incidence of chronic postoperative inguinal pain (CPIP). Resorbable meshes are relatively novel and have not yet been used for this indication in this population. Therefore, currently data on safety, effectiveness, and feasibility of this product in a prophylactic setting should be evaluated. This study aims to evaluate safety, effectiveness, and feasibility, and to provide the first estimates to assess feasibility and necessity of future randomized trials.
Objective: The primary objective of current pilot study is evaluate safety in terms of mesh related complications. Secondary, the efficacy of slowly-resorbable TIGR mesh by measuring pain reduction during exercise on the numeric rating scale, sport resumption, physical functioning, CPIP and recurrences of inguinal-related groin pain will be evaluated. However, outcomes will be exploratory and not conclusive.
Study design: Single armed prospective pilot study.
Study population: Patients 18 years or older, with inguinal-related groin pain undergoing TEP treatment.
Intervention: Included patients will undergo endoscopic TEP procedure for inguinal-related groin pain. During this procedure a slowly-resorbable TIGR® Matrix mesh will be implanted instead of a non-resorbable polypropylene mesh, which is used in current standard practice.
Main study parameters/endpoints: The primary endpoint is the safety of placement of the synthetic, slowly-resorbable TIGR® Matrix mesh in patients with inguinal-related groin pain undergoing TEP procedure in terms of intra-operative and postoperative complications.
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, persistent pain, CPIP and mesh contractures. A higher recurrence rate may be a potential risk of this product compared to non-resorbable mesh.

Doel van het onderzoek

Totally extraperitoneal endoscopic reinforcement with slowly-resorbable TIGR Matrix mesh in patients with inguinal-related groin pain is effective.

Onderzoeksopzet

3 weeks, 30 days, 6 weeks and 12 weeks postoperatively

Onderzoeksproduct en/of interventie

Totally extraperitoneal endoscopic reinforcement with slowly-resorbable TIGR Matrix mesh

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Athletes with inguinal-related groin pain, as defined in the Doha agreement (6) i.e. “pain location in the inguinal canal region and tenderness of the inguinal canal”, that was not sufficient resolved with standard conservative treatment of at least 2 months, undergoing elective TEP procedure.
- Frequency sports activity >2 / week.
- Age ≥ 18 years.
- Signed informed consent by patient.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Inguinal or femoral hernia.

- Previous inguinal hernia surgery.
- Patient with clearly more complaints due to an adductor-related groin pain instead of the inguinal-related groin pain as examined by clinician after 2 months of conservative treatment.
- Existing CPIP.
- Nerve entrapment as assessed by clinician.
- Referred spinal pain.
- Apophysitis or avulsion fracture of pelvic bone in the groin area.
- Disorders to the hip joint or bursitis.
- Intra-abdominal disorders including urologic, gynecologic or bowel pathology.

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:	30-06-2021
Aantal proefpersonen:	45
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: 52055
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9386
CCMO	NL77449.078.21
OMON	NL-OMON52055

Resultaten