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

No registrations found.

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

Summary

ID

NL-OMON22732

Source
Nationaal Trial Register

Brief title
SWIFT

Health condition

Inguinal-related groin pain

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

complications

Secondary outcome

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

Study description

Background summary

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.

Study objective

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

Study design

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

Intervention

Totally extraperitoneal endoscopic reinforcement with slowly-resorbable TIGR Matrix mesh

Contacts

Public
Erasmus MC
Floris den Hartog

+31 10 704 36 84
Scientific
Erasmus MC
Floris den Hartog

+31 10 704 36 84

Eligibility criteria

Inclusion criteria

- 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.

Exclusion criteria

- 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.

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):	30-06-2021
Enrollment:	45
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: 52055
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results