

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

No registrations found.

<b>Ethical review</b>	Not applicable
<b>Status</b>	Pending
<b>Health condition type</b>	-
<b>Study type</b>	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**

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## **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  $\geq$  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
<b>Control:</b>	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