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

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The objective of this study is to collect additional data on the safety and performance of the slowly-resorbable TIGR® mesh in patients undergoing TEP for IGRP.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON52055

Source
ToetsingOnline

Brief title
SWIFT study

Condition

- Other condition
- Soft tissue therapeutic procedures

Synonym
Inguinal-related groin pain

Health condition

Inguinal-related groin pain, sportershernia

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Novus Scientific AB

Intervention

Keyword: Inguinal-related groin pain, Mesh, Resorbable, Totally extraperitoneal (TEP)

Outcome measures

Primary outcome

The primary outcome measure is pain during exercise on the numeric rating scale (NRS), where 0 is no pain and 10 is the most extreme pain imaginable. Pain will be measured during their pre-injury sport and at their pre-injury duration and intensity.

Secondary outcome

The secondary outcome measures will be the following validated questionnaires and scores:

- Safety in terms of intra-operative and postoperative complications.

Intra-operatively the feasibility of the product in this setting will be assessed, the time of implantation of the mesh will be recorded, any problems encountered by the researcher after each procedure will be asked (feasibility of TIGR® Matrix (ease and practicality of use). Intraoperative complications (bleeding, lesion of ductus deference, other) and post-operative complications will be recorded, including surgical site occurrence (SSO) according to the Ventral Hernia Working Group (surgical site infection (SSI), seroma, wound dehiscence, enterocutaneous fistula, wound cellulitis, non-healing incisional

wound, fascial disruption, skin or soft tissue ischemia, skin or soft tissue necrosis, wound serous or purulent drainage, stitch abscess, seroma, hematoma and infected or exposed mesh), SSOs requiring a procedural intervention (SSOPI) defined as wound opening or debridement, suture excision, percutaneous drainage, or mesh removal.

- Sport resumption (timespan (in weeks) until resuming full level of sport activity in athletes (in frequency and intensity);
- The rate of CPIP using the validated Inguinal Pain Questionnaire (IPQ v1.0 2008)(37, 38), where a lower score indicates fewer CPIP complaints and a higher score indicates more CPIP complaints;
- The confidence in return to sport levels according the validated Injury-Psychological Readiness to Return to Sport (I-PRRS v1.1 October 2018) scale, in which a low score indicates a low confidence in return to sports and a high score indicates a high confidence in return to sports (39);
- Symptoms, activity limitations, participation restrictions and quality of life using the validated Copenhagen Hip and Groin Outcome Score, in which a low score indicates few symptoms, few acitivity limitations, little participation restrictions and a high quality of life. A high score indicates many symptoms, many activity limitations, many participation restrictions and a low quality of life (HAGOS v1.0 August 2013) (40, 41);
- Recurrences of inguinal-related groin pain.

Study description

Background summary

Groin pain is a common complaint among high-performance athletes. The estimated occurrence of groin pain in athletes is 5% to 28% and is most seen in hockey and soccer players, but can also be seen in non-athletes. In some cases there is no clear pathology that causes this groin pain. In these cases, inguinal-related groin pain might be present. Inguinal-related groin pain presents with acute or chronic groin pain to the lower abdominal muscles, pubic symphysis and adductor musculature which is caused by and exacerbated with vigorous sport or physical activity.

After other causes of groin pain are excluded by history taking, physical examination and medical imaging, adequate treatment is important for fast recovery and resumption of sport activities. Conservative options for treatment of inguinal-related groin pain consist of physical therapy and rehabilitation programmes. Other non-operative management strategies are plasma enriched protein and steroid injections. Surgical treatment should be considered when conservative treatment has failed. Surgical options include endoscopic totally extraperitoneal (TEP) procedure with mesh. Promising results in fast resumption of sport activities after TEP procedure for inguinal-related groin pain are shown in the literature.

The most frequent used method for TEP procedure is with a non-resorbable mesh. However, the use of a non-resorbable mesh may cause problems concerning mesh contractures, chronic postoperative inguinal pain (CPIP) and its inability to grow with the patient. Although in experience hands the risk of these complications is low, patients with inguinal-related groin pain are relatively young and this foreign body will remain in place for life. The slowly-resorbable TIGR® Matrix mesh will stimulate collagen formation, which will take over the function of the mesh i.e. reinforcement of the abdominal wall. Therefore, the advantage of resorbable mesh over non-resorbable mesh is that the amount of foreign material persisting in the host is reduced, avoiding potential risks associated with a non-resorbable mesh, but without compromising the biomechanical resistance of the mesh.

We propose a single arm prospective pilot study to evaluate the safety, effectivity, and feasibility of the slowly-resorbable TIGR® Matrix mesh in patients presenting with inguinal-related groin pain undergoing TEP procedure. Based on these results the feasibility and necessity of a superiority or non-inferiority trial may be determined on estimated prevalence rates. The results of present study will be exploratory and not conclusive.

Study objective

The objective of this study is to collect additional data on the safety and performance of the slowly-resorbable TIGR® mesh in patients undergoing TEP for

IGRP.

Study design

A multicenter single arm prospective phase II study

Intervention

TEP procedure for inguinal-related groin pain will be performed. 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.

Study burden and risks

Patients/participans with inguinal-related groin pain undergoing TEP procedure will receive a slowly-resorbable TIGR® Matrix mesh instead of a non-resorbable mesh.

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.

During the follow-up, participants will visit the outpatient clinic four times. During these visits physical investigation will be performed. Also, the participant will fill in two questionnaires at different times during the follow-up.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

- Athletes with inguinal-related groin pain, as defined in the Doha agreement 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.
- Wish to return to pre injury sports.

Exclusion criteria

- Inguinal or femoral hernia on ultrasound imaging.
- 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 Chronic Postoperative Inguinal Pain (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.
- Inadequate knowledge of the Dutch language.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	13-09-2023
Enrollment:	57
Type:	Actual

Medical products/devices used

Generic name:	TIGR Matrix slowly-resorbable mesh
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	04-08-2022
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Approved WMO Date:	04-04-2024
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 22732
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL77449.078.21
Other	NL9386