Slowly-resorbable TIGR® Matrix mesh (Novus Scientific, Uppsala Sweden) for totally extraperitoneal (TEP) endoscopic reinforcement of inguinal-related groin pain.

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

Ethical review	Not approved
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON49459

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 objective is to determine the efficacy of the slowly-resorbable TIGR® mesh, measured through the timespan (in weeks) until resuming full level of sport activity (in frequency and intensity) in athletes after TEP surgery with slowly-resorbable TIGR® mesh placement.

Secondary outcome

The secondary endpoints will be the rate of CPIP using the Inguinal Pain Questionnaire (IPQ), symptoms, activities limitations, participation restrictions and quality of life using the Copenhagen Hip and Groin Outcome Score (HAGOS), recurrences of inguinal-related groin pain, SSI, SSO, seroma, hematoma, adhesions, fistula and foreign body reactions.

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.

Therefore, we propose a single arm prospective study to evaluateassess the effectivity, safety and feasibility of the slowly-resorbable TIGR® Matrix mesh in patients presenting with inguinal-related groin pain undergoing TEP procedure.

Study objective

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

Study design

This study will be designed as a prospective, multicenter, single-arm (cohort) trial. Patients with inguinal-related groin pain undergoing TEP procedure will receive slowly-resorbable TIGR® Matrix mesh instead of a non-resorbable mesh.

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

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

Doctor Molewaterplein 40
Rotterdam 3015GD
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

Doctor Molewaterplein 40
Rotterdam 3015GD
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

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.

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.

Study design

Design

Study phase: 4

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	40
Type:	Anticipated

Medical products/devices used

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

Ethics review

Not approved

Date:	25-05-2020
Application type:	First submission
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: 22090
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL70724.078.19
Other	NL7910
OMON	NL-OMON22090