

Sportsmen, TEP repair versus Endoscopy trial

Published: 13-07-2006

Last updated: 20-05-2024

The objective of this study is to demonstrate the effectivity of TEP repair in the treatment of a sportman's hernia.

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

Summary

ID

NL-OMON29790

Source

ToetsingOnline

Brief title

SporTEr trial

Condition

- Other condition
- Therapeutic procedures and supportive care NEC

Synonym

dilated internal ring, sportman's hernia

Health condition

sportblessures

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Athletic injuries (MESH), Sportman's hernia, Surgery (MESH), Total extraperitoneal repair

Outcome measures

Primary outcome

The procentual difference in pain reduction between treatment of a sportman's hernia with TEP repair and diagnostic endoscopy is based on VAS, MSQ and exercise test scores measured pre- and postoperative and VRCS scores measured postoperatively.

Secondary outcome

Quality of life: Euroqol, MOS SF-36, time until resumption of normal daily activities and work measured with a Activities of Daily Life (ADL) questionnaire.

Time after surgery until resumption of unrestricted athletic activity, level of athletic activity at the time of resumption (Tegner scale of activity), pain during athletic activity (VAS).

Detection of recurring episodes of groin pain using anamnesis and physical examination at post-operative polyclinic visits.

Study description

Background summary

The sportman's hernia is a common cause of prolonged injury and results in significant reduction of sporting activity. In professional athletes this injury is commonly treated with endoscopic inguinal hernia repair via the totally extra peritoneal method, or TEP repair. Different studies have reported high rates of return to unrestricted athletic activity after surgery. However, the effect of a TEP repair has never been researched in a prospective and randomised controlled trial. In this study patients are randomized in a intervention group for TEP repair or in a control group for diagnostic endoscopy of the groin region.

Study objective

The objective of this study is to demonstrate the effectivity of TEP repair in the treatment of a sportman's hernia.

Study design

In a prospective, single-blinded, controlled trial, sporters clinically diagnosed with sportman's hernia are randomised for TEP repair or diagnostic endoscopy.

Intervention

The intervention consists of TEP repair compared to diagnostic endoscopy.

Study burden and risks

The risks of this study are the complications which may occur during surgery, as consequence of the surgery itself or as as consequence of general anaesthesia. The benefit of participation in the study is a speedy recovery and resumption of sporting activity as a result of surgery.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

Male subjects, age 18-50 years;

Undiagnosed groin pain for at least 3 months;

Pain in the groin region, worsening during athletic activity;

Signed informed consent.

Exclusion criteria

Professional athletes;

Bilateral groin pain;

Clinically recognizable inguinal hernia;

Patients with a history of scrotal hernia, inguinal hernia repair, prostatectomy,

Pfannenstiel's-incision, preperitoneal surgery or abdominal bladder surgery;

Patients with a contra-indication for endoscopy.

Study design

Design

Study type: Interventional

Intervention model: Parallel

Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Placebo
Primary purpose:	Treatment

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	09-01-2006
Enrollment:	80
Type:	Anticipated

Ethics review

Approved WMO	
Date:	13-07-2006
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

No registrations found.

In other registers

Register	ID
CCMO	NL12636.078.06