Male Infertility After Totally ExtraPeritoneal Hernia Repair (TEP)

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The primary aim of this study is to examine/determine the effect of Totally ExtraPeritoneal (TEP) endoscopic hernia repair on male fertility. To measure this outcome, we examine testicular perfusion, volume, semen quality and blood levels of...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON38181

Source
ToetsingOnline

Brief title
The Main Study

Condition

- Other condition
- Sexual function and fertility disorders
- Skin and subcutaneous tissue therapeutic procedures

Synonym
fertility, Groin Hernia Repair

Health condition

liesbreuken en endoscopische liesbreukoperaties

Research involving
Human

Sponsors and support

Primary sponsor: Diakonessenhuis Utrecht
Source(s) of monetary or material Support: De Stichting Wetenschappelijk onderzoek Diakonessenhuis Utrecht (SWODU) is gevraagd om een financiele bijdrage. Deze is echter nog niet toegezegd.

Intervention

Keyword: Fertility, Herniorrhaphy, Meshrepair, Perfusion

Outcome measures

Primary outcome

Testicular perfusion after a Totally ExtraPeritoneal (TEP) endoscopic hernia

repair.

Secondary outcome

- Testicular volume after TEP

- Sperm quality and quantity after TEP

- FSH, LH, testosteron and inhibin B serum levels

Study description

Background summary

Inguinal hernia repair (or herniorrhaphy) is the most frequently performed operation in general surgery. Men have a lifelong risk of 27% to undergo inguinal herniorrhaphy.
An estimated 80% of these hernia operations involve placement of a knitted polypropylene monofilament mesh prosthesis to patch the defect in the floor of the inguinal canal. Subsequently, the prosthetic mesh induces an acute inflammatory reaction followed by a chronic foreign-body fibroblastic response that creates scar tissue and imparts strength to the floor.
Due to the close contact between mesh and the structures of the spermatic cord, these changes may also alter the reproductive structures - and therefore- fertility in maile patients. One of the complications after hernia repair is ischemic orchitis resulting in testicular infarction and atrophy. Another reported complication is seminal tract obstruction resulting in obstructive

azoospermia.
Regardless of surgical technique, little clinical information is available regarding the long-term effects of the polypropyleen mesh on the vas deferens and other structures within the spermatic cord and therefore on fertility. Parameters to measure fertility and function of reproductive structures are sperm quality (and quantity), testicular perfusion and volume, serum hormones (FSH, LH, testosteron, inhibine B).
In his prospective observational cohort study these parameters will be measured before and 6 months after a TotallyExtraperitoneal Endoscopic hernia repair (TEP). The primary aim of this study is to investigate the interaction between mesh in TEP repair and male fertility.

Study objective

The primary aim of this study is to examine/determine the effect of Totally ExtraPeritoneal (TEP) endoscopic hernia repair on male fertility. To measure this outcome, we examine testicular perfusion, volume, semen quality and blood levels of testosteron, LH, FSH, inhibin B (blood) levels after a TEP.

Study design

The study design is a longitudinal, observational, prospective cohort study

Study burden and risks

There are no additional risks associated with this observational study compared to 'regular' hernia surgery and treatment. Peroperative and perioperative care for patients who participate in this trial is also not different from regular per- and perioperative care.

Contacts

Public
Diakonessenhuis Utrecht

Postbus 1002
3700 BA Zeist
NL
Scientific
Diakonessenhuis Utrecht

Postbus 1002
3700 BA Zeist
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- Male patients * 18 years of age
- With a primary, bilateral hernia inguinalis
- Male patients with an unilateral hernia inguinalis and ipsilateral mono-testicle
- Nyhus classification II and III

Exclusion criteria

- Male patients older than 60 years of age
- Nyhus classification I and IV
- Scrotal or femoral hernia's
- Hydrocele or varicocele
- Strangulated hernia
- ASA classification * III
- Previous medical history of:
* testicular infection(s), testicular torsion, cryptorchidism
* Inguinal, scrotal, testicular of prostate surgery
* Radiotherapy of pelvic region
* Diabetes/vasculitis
* Cystic Fibrosis
* Fertility problems and/or treatment and erection disorders
- Use of gonadotrofine medication
- Use of anabolic steroids

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-03-2010
Enrollment:	76
Type:	Actual

Ethics review

Approved WMO

Date:	11-03-2010
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO

Date:	16-03-2012
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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: 29194
Source: NTR
Title:

In other registers

Register	ID
Other	De trial is geregistreerd in het trialregister (trialregister.nl). Op dit moment is er nog geen definitief identificatienummer toegediend. Kandidaatnummer is NTR7753
CCMO	NL30818.100.09
OMON	NL-OMON29194