MALE INFERTILITY AFTER TOTALLY EXTRAPERITONEAL (TEP) ENDOSCOPIC HERNIA REPAIR.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON29194

Source
Nationaal Trial Register

Brief title
MAIN studie

Health condition

Engels:
- inguinal hernia
- Totally Extraperitoneal (TEP) endoscopic hernia repair
- mesh
- fertility
- testicular perfusion

Nederlands:
- liesbreuk
- matje
- Totaal Extraperitoneale (TEP) laparoscopische liesbreukcorrectie
- Fertiliteit
- testiculaire perfusie

Sponsors and support

Primary sponsor: Diakonessenhuis Zeist (hernia Centre)

Prof. Lorentzlaan 37,
3707 HL Zeist
The Netherlands
Source(s) of monetary or material Support: SWODU, Stichting Wetenschappelijk Onderzoek Diakonessenhuis

Intervention

Outcome measures

Primary outcome

Testicular perfusion after a Totally ExtraPeritoneal (TEP) endoscopic hernia repair.

Secondary outcome

1. Testicular volume after TEP;

2. Sperm quality and quantity after TEP;

3. FSH, LH, testosteron and inhibin B serum levels.

Study description

Background summary

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 who undergo (Totally Extraperitoneal endoscopic) hernia surgery.

In this study parameters of male fertility, as testicular perfusion and volume, sperm quality and hormone levels in blood, will be evaluated before and 6 months after TEP hernia surgery.

Study objective

The hypothesis is that a mesh used in Totally Extraperitoneal Endoscopic Hernia repair (TEP) has no effect on male fertility.
The "0" hypothesis is that there is no difference in testicular perfusion (primary objective) before and after TEP and that there is no difference in testicular volume, semen quality and serum hormone levels (FSH, LH, inhibine B, testosterone).

Study design

1. Before surgery (baseline);

2. 6 months after surgery.

Intervention

1. 2x blood analysis: FSH, LH, testosterone and Inhibin B;

2. 2x sperm analysis;

3. 2x Testicular ultrasound (perfusion and volume).

All parameters are evaluated before surgery and 6 months after surgery.

Contacts

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Eligibility criteria

Inclusion criteria

1. Male patients, 18 years of age or older and younger than 60 years;

2. Patients with a primary, bilateral hernia;

3. Nyhus classification II or III.

Exclusion criteria

1. Male patients older than 60 years of age;

2. Nyhus classification I and IV;

3. Scrotal or femoral hernia's;

4. Hydrocele or varicocele;

5. Incarcerated hernia;

6. ASA classification ¡Ý III;

7. Previous medical history of:

A. Testicular infection(s), testicular torsion, cryptorchidism;

B. Inguinal, scrotal, testicular of prostate surgery;

C. Radiotherapy of pelvic region;

D. Diabetes;

E. Cystic Fibrosis;

F. Fertility problems and/or treatment, erection disorders or (other) problems in sexual function.

8. Use of gonadotrofine medication;

9. Use of anabolic steroids.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)

Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2010
Enrollment:	76
Type:	Anticipated

Ethics review

Positive opinion

Date:	11-02-2010
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 38181
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL2091
NTR-old	NTR2208
CCMO	NL30818.100.09
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON38181

Study results

Summary results
N/A