The influence of laparoscopic hernia repair on male fertility

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Sexual function and fertility disorders
Study type	Observational non invasive

Summary

ID

NL-OMON35627

Source
ToetsingOnline

Brief title
FLIRT

Condition

- Sexual function and fertility disorders
- Soft tissue therapeutic procedures

Synonym
groin hernia, inguinal hernia

Research involving
Human

Sponsors and support

Primary sponsor: Slotervaartziekenhuis
Source(s) of monetary or material Support: verzoek tot financiering zal gedaan worden bij SKWOSZ (stichting klinisch wetenschappelijk onderzoek slotervaartziekenhuis)

Intervention

Keyword: fertility, hernia, laparoscopic, repair

Outcome measures

Primary outcome

The main outcome of this pilot study is the presence of antisperm antibodies.

Secondary outcome

The secondary outcome is semen quality, defined by the World Health

Organization (WHO) by 5 criteria:

• Volume

• Sperm count

• Concentration

• Motility

• Morphology

Study description

Background summary

Groin herniorrhaphy is the most common operation performed by general surgeons. Annually over 20 million groin hernias are repaired worldwide. In the Netherlands 30,000 groin hernia repairs are done annually. The lifetime risk of developing a groin hernia is 3% in males. Symptoms of a groin hernia are pain, discomfort or cosmetic complaints.
There are many different techniques to repair a groin hernia. The conventional technique is the open suture technique. The skin is opened, the hernia is reduced and primarily closed. Recurrence rates after suture repair have been reported as high as 40%. In the 1970s Lichtenstein introduced the open tension-free repair, utilizing mesh to reinforce the posterior wall of the inguinal canal. He reported a recurrence rate that was as low as 0.7%. Due to this low recurrence rate, this technique gained much popularity, and it is until this day regarded as the golden standard. In the early 1990s laparoscopic techniques were introduced for groin hernia repair. With this technique three

small incisions are made. Through a posterior approach the posterior wall of the inguinal canal is reinforced by mesh. The recurrence rates after laparoscopic repair found in the literature are much alike open tension-free mesh repair.
This mesh is positioned close by the funiculus spermaticus. Through the funiculus spermaticus runs the spermatic cord. The foreign body (mesh) induces a foreign body response of structures closely positioned to this mesh, such as the funiculus spermaticus, resulting in scar tissue. This response is a key element of the reinforcement of the posterior wall of the inguinal canal. The effect of this foreign body response and scar tissue on the fertility in males however, is unknown. Literature shows that testicular volume, testicular perfusion and diameter of the lumen of the vas deferens decrease. Also, due to the foreign body response of the funiculus spermaticus the blood-testis barrier is damaged. This may result in the generation of antisperm antibodies. These antibodies influence the male fertility.
If this pilot shows the presence of antisperm antibodies after laparoscopic inguinal hernia repair, we will continue researching the presence of antibodies after different techniques, such as the open tension-free mesh repair technique. The results of this pilot study will therefore influence the general recommendations in techniques used in fertile men with a groin hernia.

Study objective

This study is a pilot study to examine the presence of antisperm antibodies after laparoscopic groin hernia repair in men.
The hypothesis of this pilot study is: After laparoscopic groin hernia repair with a mesh, antisperm antibodies can be detected in semen.

Study design

Operation technique: the inguinal hernia will be repaired laparoscopically by either the TEP or the TAPP technique. The repair will be done under general anaesthesia. Three small incisions will be made in the abdomen, to introduce the instruments. During the TEP technique all the instruments will remain outside the abdominal cavity, but in the preperitoneal space. The instrument will create space towards the inguinal canal in such a way that the peritoneum will remain closed. The inguinal hernia will be reduced and a mesh will be positioned to increase the strength of the posterior wall of the inguinal canal. During the TAPP technique the instruments will be introduces in the abdominal cavity. The peritoneum will be opened, and the same preperitoneal space will be entered. The hernia will be reduced and the mesh will be positioned. After positioning of the mesh, the peritoneum will be closed by a suture. The results of the TEP and TAPP technique are comparable.

Semen analysis: The semen analysis will be done several days prior to surgery and 6 months after surgery. The patient will produce the semenmonster and

deliver it to the Clinical Laboratory at the Slotervaartziekenhuis. The quality of the semen will be analyzed according to the WHO-criteria (see secondary outcomes) and the presence of antisperm antibodies will be evaluated. These antibodies will be detected by the SperMar test. During this test a reagens will be applied to the sperm cells. This reagens attaches to possible antisperm antibodies and antisperm antibodies can be made visible. When the second SperMar test shows presence of antisperm antibodies, the patient will be requested to produce a third semenmonster. This semenmonster will also be produced at home, and delivered at the IVF-centre of the VU Medical Centre. In the VU Medical Centre the Immunobead test will be done. In this test also, a reagens will be applied to the sperm cells. This reagens shows the presence of antisperm antibodies and also the type of antibodies

Power-analysis: In the pre-operative semen analysis no presence of antisperm antibodies is expected. The possible risk factors that may initiate the presence of antibodies, like scrotal trauma or immunodepression, are used as exclusion criteria. We would like to estimate a difference of 10% between the pre-operative and post-operative semen analysis with $\alpha = 0.05$ and power = 0.8. We therefore need approximately 80 patients.

Statistical analysis: to estimate the difference in presence of antisperm antibodies a chi-square test will be used.

Semen production: The patient should abstain himself from ejaculation in the three days prior to producing the semenmonster. The semenmonster is supposed to be produced by masturbation. To guarantee the highest possible quality of the semenmonster, the following guidelines need to be considered:
• The patient needs to empty his bladder before masturbation. He needs to rinse his penis with water, but not with soap. The penis should dried by shaking of the water (not by drying it with a towel).
• The semen will be damaged by sudden drop in temperature. The jar needs to be pre-heated to room temperature by holding the jar in the hands, or by putting the jar in pocket.
• The total amount of sperm needs to be caught in the jar. The inside of the jar is sterile and is not supposed to be touched by the fingers.
• The jar needs to be firmly closed by the lid.
• During transportation to the hospital sudden drop in temperature needs to be avoided. The jar needs to be wrapped by aluminium foil and kept close to body heat during winter. The jar containing the sperm needs to be delivered within 1 hour at the Clinical Laboratory at the Slotervaartziekenhuis.

In case of presence of antibodies in the second semen analysis, a third semen analysis needs to be done at the VU Medical Centre. The semenmonster needs to be produced at home, in the same way as described above. The semenmonster needs to be delivered within two hours at the IVF-centre at the VU Medical Centre.

Inclusion criteria:

• Primary inguinal hernia
• Male gender
• Age > 18 years
• Elective surgery
• Informed consent
• Both testes descended

Exclusion criteria
• Fertility problems in past history
• Scrotal trauma
• Surgery in groin area in past history
• Immune depression
• Severe comorbidity
• Palpable lesion in scrotum

Study burden and risks

not applicable

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

age > 18 years
male gender
descended testes
first inguinal hernia
elective surgery

Exclusion criteria

fertility problems in past history
scrotal trauma
surgery in groin area in past history
Immunodepression
ASA-class > 3
Non descended testes
Palpable abnormalities in testes

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	18-04-2011
Enrollment:	80

Type:	Actual

Ethics review

Approved WMO Date:	10-11-2010
Application type:	First submission
Review commission:	METC Slotervaartziekenhuis en Reade (Amsterdam)

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	NL28176.048.10