Effects of vaginal prolapse surgery on innervation of the vagina

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1. To assess the effects of prolapse surgery on vaginal nerve density2. To measure the association between changes in vaginal nerve density and changes in pelvic floor function

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Vulvovaginal disorders (excl infections and inflammations)
Study type	Observational invasive

Summary

ID

NL-OMON37503

Source
ToetsingOnline

Brief title
VIVA trial

Condition

- Vulvovaginal disorders (excl infections and inflammations)
- Obstetric and gynaecological therapeutic procedures

Synonym
Pelvic organ prolapse

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Innervation, Prolapse, Surgery, Vaginal

Outcome measures

Primary outcome

The effects of prolapse surgery on vaginal nerve density quantified in vaginal epithelial layer biopsies (diameter 4 mm) taken before surgery and at 6 weeks and 6 months after surgery. Biopsies will be taken from the vaginal epithelial layer at both the operated compartment and the opposite vaginal wall.

Secondary outcome

Pelvic floor function measured using the UDI-6, IIQ-7 and PISQ-12 questionnaires before and 6 months after surgery.

Study description

Background summary

Vaginal prolapse surgery is intended to restore abnormal pelvic floor function by restoring anatomical abnormalities of the vagina and its surrounding visceral organs. The surgical trauma that occurs during such correction may result in damage to vaginal innervation and vascularisation which could explain why pelvic floor dysfunction persists or develops in some patients who undergo vaginal prolapse surgery. Our group developed a validated technique to measure the sensibility of the vaginal wall. It is possible that this technique measures more than the vaginal sensibility alone because measurements can be influenced by other neurological or emotional factors like concentration, sensibility input from other parts of the body, anticipation to a stimulus etc. To objectively assess the effect of surgical trauma on the vaginal sensibility we propose a study where we will measure the vaginal nerve density before and after prolapse surgery.

Study objective

1. To assess the effects of prolapse surgery on vaginal nerve density
2. To measure the association between changes in vaginal nerve density and

changes in pelvic floor function

Study design

An observational prospective pilot study

Study burden and risks

Before surgery biopsies will be taken under general anaesthesia therefore causing no extra burden. Surgery time will not be prolonged and there is no expectation that taking two biopsies will influence prolapse surgery. During the follow-up at six weeks (routine post-operative consultation) and six months (one extra visit) after surgery two biopsies will be taken under local anaesthesia in a controlled clinical setting. Informed consent will be obtained.

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

- Patients undergoing primary prolapse surgery because of vaginal prolapse stage * 2 in either the anterior or posterior compartment.
- Sexually active women, sexually active meaning:
o Patients who are sexually active before surgery
o Patients who are not sexually active before surgery but plan to become sexually active after surgery

Exclusion criteria

- Previous pelvic surgery
- Previous pelvic irradiation
- Unwilling to return for follow-up or language barriers
- Presence of immunological / haematological disorders interfering with recovery after surgery
- Neurologic disorders, neuropathy
- Abnormal ultrasound findings of uterus or ovaries.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	16-07-2012
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO Date:	19-06-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	18-07-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC

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: 22450
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL40356.018.12
OMON	NL-OMON22450