Effects of vaginal prolapse surgery on innervation of the vagina.

No registrations found.

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

Summary

ID

NL-OMON22450

Source
NTR

Brief title
VIVA trial

Health condition

Prolapse, Surgery, Innervation, Vagina

Sponsors and support

Primary sponsor: Academic Medical Centre (AMC)
Source(s) of monetary or material Support: Academic Medical Centre (AMC)

Intervention

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.

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

Rationale:

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.

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 population:

Sexually active women undergoing primary prolapse surgery because of single compartment vaginal prolapse stage 2 or more (ICS classification).

Main study parameters/endpoints:

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

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

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.

Study objective

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 design

Biopsies will be taken before surgery and at 6 weeks and 6 months after surgery.

Intervention

Vaginal nerve density will be 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.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients undergoing primary prolapse surgery because of vaginal prolapse stage ≥ 2 in either the anterior or posterior compartment;

2. Sexually active women, sexually active meaning:

A. Patients who are sexually active before surgery;

B. Patients who are not sexually active before surgery but plan to become sexually active after surgery.

Exclusion criteria

1. Previous pelvic surgery;

2. Previous pelvic irradiation;

3. Unwilling to return for follow-up or language barriers;

4. Presence of immunological / haematological disorders interfering with recovery after surgery;

5. Neurologic disorders, neuropathy;

6. Abnormal ultrasound findings of uterus or ovaries.

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:	Recruiting
Start date (anticipated):	01-07-2012
Enrollment:	10
Type:	Anticipated

Ethics review

Positive opinion

Date:	02-08-2012
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 37503
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3387
NTR-old	NTR3558
CCMO	NL40356.018.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON37503

Study results

Summary results
N/A