

# Effects of vaginal prolapse surgery on innervation of the vagina

Published: 19-06-2012

Last updated: 19-03-2025

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

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Vulvovaginal disorders (excl infections and inflammations)
<b>Study type</b>	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: NTR

Title:

### In other registers

Register	ID
CCMO	NL40356.018.12
OMON	NL-OMON22450