

Effects of vaginal prolapse surgery on innervation of the vagina.

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22450

Bron

Nationaal Trial Register

Verkorte titel

VIVA trial

Aandoening

Prolapse, Surgery, Innervation, Vagina

Ondersteuning

Primaire sponsor: Academic Medical Centre (AMC)

Overige ondersteuning: Academic Medical Centre (AMC)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

PO Box 22660

Jan-Paul W.R. Roovers
Department of Obstetrics and Gynaecology
Academic Medical Center (AMC)
Meibergdreef 9, H4-140-1
Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5666429

Wetenschappelijk

PO Box 22660

Jan-Paul W.R. Roovers
Department of Obstetrics and Gynaecology
Academic Medical Center (AMC)
Meibergdreef 9, H4-140-1
Amsterdam 1105 AZ
The Netherlands
+31 (0)20 5666429

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving gestart
(Verwachte) startdatum:	01-07-2012
Aantal proefpersonen:	10
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies	
Datum:	02-08-2012

Soort:

Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 37503

Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten

N/A