Effects of pelvic organ prolapse and vaginal prolapse surgery on vaginal microcirculation

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1. To investigate the intra- and inter-observer agreement in the assessment of vaginal capillary density using SDF imaging. 2. To investigate whether between patients with and without pelvic organ prolapse (POP) and in the compartment with and...

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

Summary

ID

NL-OMON39010

Source
ToetsingOnline

Brief title
VAMP-2 study

Condition

- Vulvovaginal disorders (excl infections and inflammations)

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: Microcirculation, Prolapse, Surgery, Vaginal

Outcome measures

Primary outcome

1. The intra- and inter-observer agreement of vaginal SDF imaging.

2. Differences in measurements of microcirculatory parameters between patients with and without POP and between the compartment with and without POP within a POP patient.

3. The best time interval to measure microcirculatory parameters after vaginal prolapse surgery with a first assessment of the effects of prolapse surgery on microcirculatory parameters.

Secondary outcome

nvt

Study description

Background summary

Vaginal prolapse surgery intends to correct pelvic floor dysfunction by normalizing the anatomy of the vagina and its surrounding pelvic organs. However, during surgery damage occurs to the vascularization of the vagina. Whether this damage is reversible or not has never been studied. Neither is known what the effect of prolapse itself is on the vascularisation of the vagina.
Improved understanding of the effects of vaginal prolapse and prolapse surgery on vaginal vascularisation may ultimately improve patient outcome by modifying surgical techniques or approaching patients with predicted bad outcome to alternative treatment options. Vaginal microcirculation can be evaluated using sidestream dark-field (SDF) imaging. We propose a study to investigate the intra- and inter-observer agreement in the assessment of vaginal capillary density using SDF imaging followed by a pilot study to assess the effects of vaginal prolapse on vaginal microcirculation. After this, we will investigate

the best time interval for measurement of microcirculatory parameters after vaginal prolapse surgery.

Study objective

1. To investigate the intra- and inter-observer agreement in the assessment of vaginal capillary density using SDF imaging.
2. To investigate whether between patients with and without pelvic organ prolapse (POP) and in the compartment with and without POP within the same POP patient differences exist in microcirculatory parameters.
3. To determine the best time interval to measure microcirculatory parameters after vaginal prolapse surgery with a first assessment of the effects of prolapse surgery on microcirculatory parameters.

Study design

A prospective pilot study

Study burden and risks

Measurements will be performed in an outpatient clinic of a teaching hospital, pre-operative and 2 weeks and 3 months post-operative. Each measurement will take 15 minutes. Patients will be counseled before the measurements and informed consent will be obtained. The imaging probe will be covered with a sterile disposable cap. The measurement technique is painless and will cause no harm.

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 or more

Exclusion criteria

Previous pelvic floor surgery

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-07-2013

Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	09-07-2013
Application type:	First submission
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

No registrations found.

In other registers

Register	ID
CCMO	NL44321.018.13