

A new approach to measure vaginal microcirculation.

No registrations found.

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

Summary

ID

NL-OMON23498

Source

Nationaal Trial Register

Brief title

VAMP study

Health condition

Prolapse
Surgery
Vaginal
Microcirculation

Sponsors and support

Primary sponsor: AMC

Source(s) of monetary or material Support: AMC

Intervention

Outcome measures

Primary outcome

Feasibility of SDF imaging and spectrophotometry of the vaginal wall.

Secondary outcome

The interobserver reproducibility of SDF imaging and spectrophotometry of the vaginal wall. Differences in measurements of SDF imaging and spectrophotometry between the proximal and distal part of the vagina, and between the anterior and posterior wall of the vagina.

Study description

Background summary

Rationale:

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 vascularisation of the vagina. Whether this damage is reversible or not has never been studied. Neither is known what the effects of surgical damage to vaginal vascularisation are on oxygenation of the vagina, and whether these effects depend on patient- and surgery- related characteristics.

Improved understanding of the effects of vaginal prolapse surgery on vaginal vascularisation and oxygenation 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 and oxygenation of the vaginal wall can be measured using reflectance spectrophotometry (O2C). We propose a pilot study to investigate the feasibility of SDF imaging and spectrophotometry in the vagina.

Objective:

1. To investigate the feasibility of SDF imaging and spectrophotometry of the vaginal wall;
2. To investigate the interobserver reproducibility of SDF imaging and spectrophotometry of the vaginal wall;
3. To investigate whether between the proximal and distal part of the vagina, and between the anterior and posterior wall of the vagina, differences exist in SDF imaging and spectrophotometry of the vaginal wall.

Study design:

A cross-sectional pilot study.

Study population:

Patients scheduled for primary vaginal prolapse surgery because of vaginal prolapse stage 2 or more (ICS classification).

Main study parameters/endpoints:

Primary outcome: Feasibility of SDF imaging and spectrophotometry of the vaginal wall.

Secondary outcome: The interobserver reproducibility of SDF imaging and spectrophotometry of the vaginal wall. Differences in measurements of SDF imaging and spectrophotometry between the proximal and distal part of the vagina, and between the anterior and posterior wall of the vagina.

Measurements will be performed in eight different target areas (proximal and distal in four different directions) by two researchers before and after local administration of 1:200.000 diluted adrenaline.

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

Measurements will be performed under general anesthesia therefore causing no extra burden. Surgery time will be prolonged with 5 minutes and there is no expectation that this prolongation will influence the morbidity risks of the procedure. Patients will be counseled before the measurements and informed consent will be obtained. Measurements will not influence the procedure. Local administration of 1:200.000 diluted adrenaline in the vaginal wall will not harm the patient.

Study objective

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 vascularisation of the vagina. Whether this damage is reversible or not has never been studied. Neither is known what the effects of surgical damage to vaginal vascularisation are on oxygenation of the vagina, and whether these effects depend on patient- and surgery- related characteristics.

Improved understanding of the effects of vaginal prolapse surgery on vaginal vascularisation and oxygenation 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 and oxygenation of the vaginal wall can be measured using reflectance spectrophotometry (O2C). We propose a pilot study to investigate the feasibility of SDF imaging and spectrophotometry in the vagina.

Study design

Measurements will be performed under general anesthesia right before the start of surgery.

Intervention

Measurements will be performed in eight different target areas (proximal and distal in four different directions) by two researchers before and after local administration of 1:200.000 diluted adrenaline.

Contacts

Public

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Eligibility criteria

Inclusion criteria

Patients undergoing primary prolapse surgery because of vaginal prolapse stage 2 or more.

Exclusion criteria

Previous pelvic surgery.

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):	15-06-2012
Enrollment:	50
Type:	Anticipated

Ethics review

Positive opinion	
Date:	14-06-2012
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 39375
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL3352
NTR-old	NTR3484
CCMO	NL40476.018.12
ISRCTN	ISRCTN wordt niet meer aangevraagd.
OMON	NL-OMON39375

Study results

Summary results

N/A