A new approach to measure vaginal microcirculation.

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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...

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

Samenvatting

ID

NL-OMON23498

Bron
Nationaal Trial Register

Verkorte titel
VAMP study

Aandoening

Prolapse
Surgery
Vaginal
Microcirculation

Ondersteuning

Primaire sponsor: AMC
Overige ondersteuning: AMC

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Feasibility of SDF imaging and spectrophotometry of the vaginal wall.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Previous pelvic surgery.

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	15-06-2012
Aantal proefpersonen:	50
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	14-06-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 39375
Bron: ToetsingOnline

Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A