A new approach to measure vaginal microcirculation

Published: 11-06-2012 Last updated: 19-03-2025

To investigate the feasibility of SDF imaging and spectrophotometry of the vaginal wall.

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

Summary

ID

NL-OMON39375

Source ToetsingOnline

Brief title VAMP 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

A new approach to measure vaginal microcirculation and oxygenation by

investigating the feasibility of SDF imaging and spectrophotometry of the

vaginal wall.

Secondary outcome

Not applicable

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 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 vascularisation (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 objective

To investigate the feasibility of SDF imaging and spectrophotometry of the vaginal wall.

Study design

A 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. Both measurement techniques are painless and will cause no harm.

Contacts

Public Academisch Medisch Centrum

Meibergdreef 9 Amsterdam 1105 AZ NL **Scientific** Academisch Medisch Centrum

Meibergdreef 9 Amsterdam 1105 AZ NL

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.

3 - A new approach to measure vaginal microcirculation 14-05-2025

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:	Treatment

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	11-06-2012
Enrollment:	50
Туре:	Actual

Ethics review

Approved WMO Date:	11-06-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO Date:	21-06-2012
Application type:	Amendment
Review commission:	METC Amsterdam UMC
Approved WMO Date:	12-03-2013

Application type: Review commission: Amendment 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: 23498 Source: Nationaal Trial Register Title:

In other registers

Register	ID
ССМО	NL40476.018.12
OMON	NL-OMON23498