Effects of vaginal prolapse surgery on vaginal microcirculation

Published: 15-07-2014
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To assess the effects of vaginal prolapse surgery on microcirculatory parameters measured in the vaginal wall with the use of incident dark field (IDF) imaging (Cytocam).

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

Summary

ID

NL-OMON44209

Source
ToetsingOnline

Brief title
VAMP-4 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

Differences in measurements of microcirculatory parameters in patients with POP

before and after vaginal surgery.

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 vascularization of the vagina. Whether this damage is reversible or not has never been studied. Improved understanding of the effects of vaginal prolapse surgery on vaginal vascularization may ultimately improve patient outcome by modifying surgical techniques or approaching patients with predicted bad outcome to alternative treatment options

Study objective

To assess the effects of vaginal prolapse surgery on microcirculatory parameters measured in the vaginal wall with the use of incident dark field (IDF) imaging (Cytocam).

Study design

An observational pilot study.

Study burden and risks

Measurements will be performed in a teaching hospital. 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 prolapse surgery because of vaginal prolapse stage 2 or more in either the anterior or posterior compartment.

Exclusion criteria

1. Cardiovascular disease (e.g. angina pectoris, hypertension)
2. Inflammatory disease (e.g. rheumatoid arthritis, eczema)
3. Other systemic illness (e.g. (non-) insulin dependent diabetes mellitus)
4. Medications (e.g. anticoagulants, anti-inflammatory, or immunosuppressive agents) that could influence the microcirculation

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	26-10-2014
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	15-07-2014
Application type:	First submission
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	16-06-2015
Application type:	Amendment
Review commission:	METC Amsterdam UMC

Approved WMO

Date:	19-09-2016
Application type:	Amendment
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	NL49122.018.14