Effects of local oestrogen on vaginal microcirculation in the treatment of vaginal atrophy

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1. To examine and describe the vaginal microcirculation in patients with VA in comparison to patients without VA2. To examine and describe the effect of treatment with local oestrogen on the vaginal microcirculation.

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

Summary

ID

NL-OMON41036

Source
ToetsingOnline

Brief title
VAMP-3 study

Condition

- Vulvovaginal disorders (excl infections and inflammations)

Synonym
Vaginal atrophy

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, Oestrogen, Vaginal atrophy

Outcome measures

Primary outcome

Differences in measurements of microcirculatory parameters in patients with VA

and before and after treatment with local oestrogen.

Secondary outcome

n/a

Study description

Background summary

Vaginal atrophy (VA) is a condition that commonly affects postmenopausal women. The aetiology of VA is mainly explained by the decline in levels of circulating oestrogen associated with the menopausal transition, which causes the epithelium of the vagina to become thin and friable. The role of the vaginal microcirculation in the health of the vaginal epithelium is currently unknown. Neither is known if possible damage to the vaginal microcirculation in women with VA is reversible with the use of local oestrogen.

Study objective

1. To examine and describe the vaginal microcirculation in patients with VA in comparison to patients without VA
2. To examine and describe the effect of treatment with local oestrogen on the vaginal microcirculation.

Study design

An observational pilot study

Study burden and risks

Measurements will be performed in an outpatient clinic of 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

Women with vaginal atrophy diagnosed based on:
a. The presence of one or more of the following symptoms:
- Vaginal dryness
- Vaginal itching/irritation
- Dyspareunia
b. The presence of one or more of the following symptoms on physical examination:
- Presence of vaginal wall pallor and petechiae
- Friability of the vaginal wall (defined as any bleeding occurring during examination)

- Conization (markedly decreased elasticity)
- Absence of rugae

Exclusion criteria

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

Study design

Design

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

Primary purpose: Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-10-2014
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	16-09-2014
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	NL49119.018.14