

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

Published: 16-09-2014

Last updated: 21-04-2024

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.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Vulvovaginal disorders (excl infections and inflammations)
<b>Study type</b>	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

### 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

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