Non-invasive measurement of vaginal tissue hydration in women with and without GSM

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The primary objective is to evaluate the reproducibility of the Corneometer® as a measurement instrument to quantify hydration of the vaginal wall, evaluated by intra- and interobserver variability. The secondary objective is to measure the response...

Ethical review	Approved WMO
Status	Pending
Health condition type	Menopause related conditions
Study type	Observational non invasive

Summary

ID

NL-OMON56226

Source
ToetsingOnline

Brief title
HAVA

Condition

- Menopause related conditions

Synonym
Genitourinary syndrome of menopause (GSM), Vaginal atrophy

Research involving
Human

Sponsors and support

Primary sponsor: Bergman Clinics
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: GSM, Hydration, Measurement, Vagina

Outcome measures

Primary outcome

The main study parameter is the reproducibility of the Corneometer® as a measurement instrument to quantify hydration of the vaginal wall, evaluated by intra- and interobserver agreement.

Secondary outcome

Secondary study parameters are:

1. Response to treatment for GSM using vaginal oestrogen, as measured with the Corneometer®.

2. Differences in vaginal hydration measurements between women with and without GSM.

3.Correlations between vaginal hydration measurements and:

a. Objective measure of GSM: pH

b. Subjective measure of GSM: most bothersome symptom approach (MBS)

c. Subjective measure of improvement: Patient Global Impression of Improvement (PGI-I)

Study description

Background summary

Genitourinary syndrome of menopause (GSM) is a chronic, progressive vulvovaginal, sexual and lower urinary tract condition that affects one in two postmenopausal women. GSM is characterized by signs and symptoms that can be attributed to the lack of oestrogen inherent with menopause. The hypoestrogenic

state results in hormonal and anatomical changes in the genitourinary tract, with vaginal dryness, dyspareunia, and reduced lubrication being the most prevalent and bothersome symptoms. These symptoms often have a great impact on daily activity, sexual function and overall quality of life.

Treatment for GSM aims to restore vaginal integrity and relieve urogenital symptoms. Conservative treatment for GSM includes the use of non-hormonal vaginal lubricants and moisturizers. For more severe or persistent symptoms of GSM, standard medical treatment is vaginal oestrogen therapy, in the form of a vaginal cream, ovules, tablets or a ring. Vaginal laser therapy is a novel, alternative treatment modality for GSM.

The diagnosis and evaluation of GSM are clinical and mostly established through a thorough anamnesis and physical pelvic examination. Objective measures that evaluate GSM include vaginal pH and vaginal cytology (vaginal maturation index (VMI), vaginal maturation value (VMV), karyopyknotic index (KI)). However, cytology requires time and expertise and the relationship between these measures and clinical outcome is poor.

Treatment strategies for GSM aim to increase vaginal epithelial thickness and hydration. Objective evaluation of treatment effects should therefore evaluate these outcome measures. Vaginal epithelial thickness can be evaluated non-invasively by the focal depth using incident dark field imaging. For the assessment of hydration, however, there are no non-invasive methods available yet.

The Corneometer® (Courage + Khazaka, Köln, Germany), is a handheld lightweight probe that is widely applied for objective assessment of hydration of the outer layer of the epidermis (stratum corneum). Its main applications today are in the field of cosmetology for efficacy testing of cosmetics and skincare products. Corneometry has not been applied to the vaginal epithelium yet.

In this project, we will evaluate vaginal hydration as measured with the Corneometer®. We will study the effect of GSM and vaginal oestrogen therapy on vaginal hydration and evaluate intra- and interobserver variability.

Study objective

The primary objective is to evaluate the reproducibility of the Corneometer® as a measurement instrument to quantify hydration of the vaginal wall, evaluated by intra- and interobserver variability. The secondary objective is to measure the response to treatment for GSM with vaginal oestrogens using the Corneometer® and to relate changes in hydration to changes in yet validated outcome measurements.

Study design

The proposed research concerns an observational validation study.

Study burden and risks

Enrolled participants receive standard medical care and do not require additional visits. The technology for measuring hydration is non-invasive. Measurements will be performed during routine physical examination, which is all standard care. Measurements take less than 30 seconds, are painless and cause no harm. No additional risks are expected.

Contacts

Public
Bergman Clinics

Nijenburg 152
Amsterdam 1081GG
NL
Scientific
Bergman Clinics

Nijenburg 152
Amsterdam 1081GG
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Group 1: women with GSM

- Age: >55 years old
- Starting standard medical treatment with vaginal oestrogen
- Presence of GSM will be determined by (1) the most bothersome symptom approach (MBS: vaginal dryness, vaginal/vulvar irritation/itching, vaginal/vulvar soreness, and dyspareunia), (2) physical examination (vaginal physical examination scale (Greenadle et al. (1999)), (3) vaginal pH of 6.0 or higher.

Group 2: women without GSM
- Age: 20 - 45 years old
- Reason for attending clinic: benign gynaecological conditions

Exclusion criteria

Group 1: women with GSM
1. Prior (trans)vaginal surgery
2. (History of) oncological or pre-oncological gynaecological disease
3. Already started treatment with vaginal oestrogen

Group 2: non-GSM group
1. Signs or symptoms of GSM
2. Currently using vaginal oestrogen treatment
3. Prior (trans)vaginal surgery
4. (History of) oncological or pre-oncological gynaecological disease
5. The following vaginal conditions: lichen planus, symptomatic candidiasis, bacterial vaginosis.

Study design

Design

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

Primary purpose: Diagnostic

Recruitment

NL
Recruitment status: Pending

Start date (anticipated):	01-09-2021
Enrollment:	20
Type:	Anticipated

Medical products/devices used

Generic name:	Corneometer
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	26-04-2023
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO Date:	19-02-2025
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL77856.100.21