

Vaginal dynamic pressure measurements and vaginal sensibility (reflex) tests in asymptomatic women: an explorative study

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The primary objective of this study is to assess the dynamic vaginal pressure profile in asymptomatic women. The secondary objective is to assess vaginal reflexes in asymptomatic women.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Sexual function and fertility disorders
Study type	Observational invasive

Summary

ID

NL-OMON37744

Source

ToetsingOnline

Brief title

Vaginal dynamic pressure and reflex tests

Condition

- Sexual function and fertility disorders

Synonym

Dyspareunia, vaginismus

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Vaginal dynamic pressure, Vaginal reflexes

Outcome measures

Primary outcome

Vaginal dynamic pressures, vaginal reflexes.

Secondary outcome

N.a.

Study description

Background summary

Anno 2012, there is still no consensus about the vaginal pressure profile in asymptomatic women. Although various devices and techniques have been developed to measure vaginal pressure, none of these techniques actually measured absolute and dynamic pressure. Furthermore, the vaginal canal does not contain one uniform pressure zone, but three different pressure segments (distal, mid, proximal). Until now, the majority of studies have not attempted to distinguish pressures in the different segments of the vaginal canal. We hypothesize that dynamic vaginal pressure measurement can be a valuable tool to differentiate between female sexual disorders like dyspareunia and vaginismus. Therefore, we first want to determine the norms for dynamic vaginal pressure in asymptomatic women. In the future, based on the pressure profile, vaginismus probably can be distinguished from dyspareunia. The female reproductive tract is not simply a passive conduit for the passage of the penis, foetus, semen and menses but a responsive, active canal equipped with subtle reflectory activity. Taken the embryology in consideration, the vaginal canal originates from the same germ line as the anal canal. Therefore, we hypothesize that the vaginal canal might have similar reflexes as the anal canal. At the University Medical Center in Groningen a new technique with advanced microsensors has been developed to measure absolute dynamic vaginal pressure in different segments of the vaginal canal, and to measure vaginal reflexes as well.

Study objective

The primary objective of this study is to assess the dynamic vaginal pressure

profile in asymptomatic women. The secondary objective is to assess vaginal reflexes in asymptomatic women.

Study design

An explorative study.

Study burden and risks

There are no risks associated with participation. For the vaginal tests, a thin catheter will be placed in the vaginal canal. Next to that a small balloon will be placed in the vagina and slowly inflated with water of body temperature. As soon as the patient experiences pain, the tests will be stopped. The burden mainly consists of the time it takes to fill out questionnaires and to undergo the vaginal pressure- and reflex tests. Participants will receive a compensation.

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

Asymptomatic women

Subjects need to be 18 years or older (but not over 45 years)

Subjects need to be nulliparous

Subjects need to be able to read the Dutch language

Subjects are required to give signed informed consent

Exclusion criteria

Pregnant women

Women with a history of pelvic floor trauma/operations

Women with sexual transmitted diseases

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Other

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 22-06-2012

Enrollment: 20

Type: Actual

Ethics review

Approved WMO

Date: 12-06-2012

Application type: First submission

Review commission: METC Universitair Medisch Centrum Groningen (Groningen)

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	NL39767.042.12