Vaginal dynamic pressure measurements and vaginal sensibility (reflex) tests in women diagnosed with dyspareunia and primary vaginismus: an explorative study.

Published: 05-03-2013
Last updated: 26-04-2024

Objective(s): The primary objective of this study is to asses the dynamic vaginal pressure profile in two groups: 1) women diagnosed with dyspareunia and, 2) women with primary vaginismus. The secondary goal is to assess vaginal reflexes in women...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Sexual function and fertility disorders
Study type	Observational invasive

Summary

ID

NL-OMON39943

Source
ToetsingOnline

Brief title
Vaginal dynamic pressure and sensibility (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: Gynaecologie en chirurgie UMCG

Intervention

Keyword: Dyspareunia, Vaginal dynamic pressure, Vaginal reflexes, Vaginismus

Outcome measures

Primary outcome

Main study parameters/endpoints: Vaginal dynamic pressures, vaginal reflexes.

Secondary outcome

Not applicable.

Study description

Background summary

Female sexual pain disorders are divided into two groups, dyspareunia and primary vaginismus. Both diagnoses are based on clinical symptoms. The assumption that dyspareunia and primary vaginismus are indeed two distinct types of sexual pain disorders has been challenged, since patients often have features of both conditions.
At the University Medical Center in Groningen a new technique with advanced micro sensors has been developed to measure absolute dynamic vaginal pressure in different segments of the vaginal canal, and to measure vaginal reflexes as well. At this moment norms for absolute and dynamic vaginal pressure and vaginal reflexes in asymptomatic women are being determined in a number of asymptomatic women.
We hypothesize that absolute and dynamic vaginal pressure measurements can be a valuable tool to differentiate between dyspareunia and primary vaginismus. We hypothesize that in the future, based on the vaginal pressure profile, dyspareunia can be distinguished from primary vaginismus. Moreover, detailed knowledge about the vaginal pressure profile, and vaginal reflexes in both groups can lead to more effective treatments.

Study objective

Objective(s): The primary objective of this study is to asses the dynamic

vaginal pressure profile in two groups: 1) women diagnosed with dyspareunia and, 2) women with primary vaginismus. The secondary goal is to assess vaginal reflexes in women diagnosed with dyspareunia and women with primary vaginismus.

Study design

Study design: An explorative study.

Study burden and risks

For both study groups there are no risks associated with participation in this study. For the vaginal tests, a thin catheter will be placed in the vaginal canal. In addition, a small balloon will be placed in the vaginal canal and the balloon will slowly be 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.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1 1
Groningen 9700 RB
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1 1
Groningen 9700 RB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Women diagnosed with dyspareunia or primary vaginismus
• Subjects aged between 18-45 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

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO Date:	05-03-2013
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	NL41571.042.12