

# 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 assess 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...

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Will not start
<b>Health condition type</b>	Sexual function and fertility disorders
<b>Study type</b>	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 assess 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