The evaluation of pelvic floor muscle tone depending on how the probe was placed.

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23969

Source
NTR

Health condition

Keywords: pelvic floor muscle, vaginal probe, electromyography;
Trefwoorden: bekkenbodemspieren, vaginale sonde, elektromyografie;

Sponsors and support

Primary sponsor: Medical University in Wroclaw, Poland;
Public Higher Medical Professional School in Opole, Poland.
Source(s) of monetary or material Support: Self-financing research

Intervention

Outcome measures

Primary outcome

The electromyographic examination of pelvic floor muscles by means of intravaginal probe.

Secondary outcome

none

Study description

Background summary

none

Study objective

1. A higher resting and funtional PFM activity is observed in more distal areas from the introitus of the vagina.

2. A higher resting and funtional PFM activity is observed on the anterior wall of the vagina

Study design

Immediately after all examinations are completed for each patient

Intervention

The main objective is to determine how depth of placement of electrodes its influence on functional and resting bioelectrical activity of PFM. Moreover the probe will be placed in two different ways: toward the anterior or posterior wall of the vagina. A secondary objective is to evaluate the correlation between the activity of PFM, which was measured at various areas of vagina

The target population in this study will be healthy, nulliparous women. Lack of control group.

Participants will need to attend the examination once only. The duration
of the examination will be approximately 30 minutes.

The measurements:

Electromyographic examination of pelvic floor muscles by means of the intravaginal probe OPTIMA 3 (Sugar International, France) with 3 independent, hemispherical electrodes (recording plates).
Measurement of electrical activity of PFM will be assessed in standing position. Prior to measurements, each participant will be instructed how to perform an isolated PFM contraction and take positions used in this study. Resting and functional sEMG activity (in microvolts - µV) will be recorded.

Contacts

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Eligibility criteria

Inclusion criteria

1. Subject's consent to participate in the study,

2. Attending physician's consent,

3. Nulliparous, healthy woman,

4. Good general well-being.

Exclusion criteria

1. Contraindications to measurements (infection, menstruation),

2. Lack of subject's consent,

3. Gynecological surgeries

4. Worsening of pain ailments during examination,

5. Urinary incontinence

6. Past or present injuries within the pelvis, hip joint or spine,

7.Past or present the occurrence of pregnancy

8. Congenital and inherited anomalies of the reproductive system.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-08-2013
Enrollment:	100
Type:	Anticipated

Ethics review

Positive opinion

Date:	04-10-2013
Application type:	First submission

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
NTR-new	NL4109
NTR-old	NTR4254
Other	: none
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
none