Validation and standardization of the measurement of pelvic floor dysfunction with the MAPLE-probe

Published: 22-08-2008
Last updated: 11-05-2024

A. Determine the placement of the Maple-probe in relation to the anatomy of the pelvic floor musculature.B. Determine the normal rest tone of the pelvic floor musculatureC. Determine the normal activity of the pelvic floor musculatureD. Determine...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Genitourinary tract disorders NEC
Study type	Interventional

Summary

ID

NL-OMON39307

Source
ToetsingOnline

Brief title
Validation of the MAPLE-probe

Condition

- Genitourinary tract disorders NEC

Synonym
pelvic floor, urge urinary incontinence

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Novuqare

Intervention

Keyword: biofeedback, electrostimulation, pelvic floor, probe

Outcome measures

Primary outcome

To detect significant differences in measurement with the common used probes

and the MAPLe.

To validate the MAPLe.

To improve complaints of Urgency/Frequency and/or Urge Urinary Incontinence

Secondary outcome

Quality of Life

Study description

Background summary

Since the introduction of the manometric probe used as a perineometer by Kegel (1), many electrodes have been developed for intravaginal and intra-anal electrostimulation and biofeedback training in the treatment of pelvic floor dysfunction. Intravaginal and intra-anal electrostimulation and biofeedback training are used for treatment of urinary urge- and stress incontinence, anal dysfunction, and sexual dysfunction. For optimal treatment, knowledge of the structures that are the main targets in stimulating and in biofeedback training is needed. This knowledge of both the anatomy of the pelvic floor and physiological aspects should result in optimal design of probes. However, lack of uniformity in description of the anatomy per se, the nomenclature of the pelvic floor (2-4), and stimulation techniques is hampering such a design (5* 8). Moreover, the available, commonly used probes have been developed empirically. We developed a new probe, which has been applied for a patent In our opinion the ideal probe must be:

1. registering;
* vaginal: the puborectal muscle, the external urethral sphincter;
* anal: the puborectal muscle, the anal external sphincter, the levator ani;
2. stimulating the structures we want to stimulate: nerves or muscles;
3. shaped and sized adapted to the local anatomy (not vice versa);
4. comfortable for the patient;
5. maintaining its position;
6. the reference electrode should be incorporated;
7. suitable for sterilization;
8. durable;
9. containing rings and plates.

Study objective

A. Determine the placement of the Maple-probe in relation to the anatomy of the pelvic floor musculature.
B. Determine the normal rest tone of the pelvic floor musculature
C. Determine the normal activity of the pelvic floor musculature
D. Determine the normal straining activity of the pelvic floor musculature
E. Determine the differences between healthy volunteers and patients regarding pelvic floor function
F. Determine diference in outcome in patients treated with the commerccible available probes and the MAPLe
G. Determine the differences in outcome between EMG values of the MAPLe and EMG values of needle EMG

Study design

By way of a message on the Albinesnet and /or Cicero 100 healthy volunteers will be called. these healthy volunteers are only able to participate in this study when they did not search for help or use any medication regarding complaints of micturition, defecation and/or sexual dysfunction. These healthy volunteers will be asked if they are willing to undergo an invasive diagnostic investigation of the pelvic floor function with the Maple -probe. soem volunteers will be asked to undergo a MRI to investigate placement of probe and elektrodes.The volunteerse may apply by mail. After registration , the department of urology will send them the patient information and the informed consent.Healthy volunteers will allot a code to a fictiv number.

volunteers will be measured with the MAPLE and than with needle EMG

First patients will be measured with the commerciable available probe, than with the MAPle. Informed consent will be signed by patients..

Intervention

NA

Study burden and risks

Na

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients with pelvic floor dysfunction

Exclusion criteria

women with neurological diseases

Study design

Design

Study type:	Interventional
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-11-2009
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	22-08-2008
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO

Date:	10-10-2011
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)

	metc-ldd@lumc.nl
Approved WMO Date:	18-12-2013
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl

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	NL17997.058.08