The Influence of Pelvic floor muscle function on pessary Treatment success in patients with pelvic Organ Prolapse

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The ultimate objective is to optimize pessary treatment for all patients with pelvic organ prolapse (POP). To reach this goal, we need to learn more about the mechanisms behind success and failure of pessary treatment. Previous research suggested...

Ethical review	Approved WMO
Status	Pending
Health condition type	Uterine, pelvic and broad ligament disorders
Study type	Observational invasive

Summary

ID

NL-OMON57159

Source
ToetsingOnline

Brief title
TIPTOP study

Condition

- Uterine, pelvic and broad ligament disorders

Synonym
Prolapse; pelvic floor dysfunction

Research involving
Human

Sponsors and support

Primary sponsor: Overige Ziekenhuizen
Source(s) of monetary or material Support: FIT-UP project

Intervention

Keyword: Electromyography, Pelvic floor, Pessary, Transperineal ultrasound strain

Outcome measures

Primary outcome

The main study endpoint is the difference in pelvic floor muscle function between POP patients with successful pessary fitting, with unsuccessful pessary fitting, and healthy volunteers.

Secondary outcome

Secondary study endpoints:

• The differences, correlations, and relations between in pelvic floor muscle function measurements tools: 4D TPUS derived strain and myofeedback measurements (MAPLe and TMSI)

• Relationship between the functional measurements (TPUS, MAPLe and TMSI) and the clinical symptoms (PFIQ-7 and PDFI-20)

• Anatomical differences between POP patients with successful pessary fitting, with unsuccessful pessary fitting, and healthy volunteers

Study description

Background summary

Pelvic organ prolapse (POP) is a common problem in middle aged women. In the Netherlands, the prevalence of symptomatic POP in women between 45-85 years is 11.4%. A pessary is a relatively inexpensive treatment option that reduces POP symptoms. However, the success rates of pessary fitting range between 58 and 73% for the regular ring pessary. Furthermore, researchers and clinicians have different thoughts about the position of a pessary inside the body and research into risk factors associated with unsuccessful pessary fitting shows conflicting results. Imaging techniques can be used to evaluate the position of

a pessary. A recent study within our group using upright magnetic resonance imaging (MRI) suggests that the pessary is supported by the pelvic floor muscles.
Considering these findings, the function of the pelvic floor muscles appears to be of essence to the success of pessary treatment. Myofeedback measurements have been used to investigate the function of the pelvic floor muscles, especially in pelvic floor physiotherapy. Moreover, 4 dimensional (4D) transperineal ultrasound (TPUS) derived strain assessment has emerged as a non-invasive tool to investigate both the pelvic floor function and anatomy.

There is a large amount of unknowns considering the support of a pessary. Insight in these unknowns may be useful to optimize the pessary treatment and reduce the complication rate and the amount of unsuccessful fittings.

Study objective

The ultimate objective is to optimize pessary treatment for all patients with pelvic organ prolapse (POP). To reach this goal, we need to learn more about the mechanisms behind success and failure of pessary treatment. Previous research suggested that the pelvic floor has a supporting role for the pessary. From this follows the hypothesis that pelvic floor muscle function influences the success chances for pessary treatment in patients with POP. More specifically, that a better pelvic floor muscle function is associated with a higher chance of pessary treatment success. With the current study the first step towards testing this hypothesis is set. Hence, the main objective of this study is to identify differences in pelvic floor muscle function between patients with POP that have a successful pessary treatment, patients with POP that have an unsuccessful pessary treatment, and healthy controls.
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The secondary objectives are:
• to evaluate the different tools for pelvic floor muscle function quantification (myofeedback and TPUS) for the assessment of pelvic floor function in POP patients
• to evaluate the relation pelvic floor muscle function to clinical POP symptoms
• to identify pelvic (floor) anatomy characteristics that play a role in the success and failure of pessary treatment in POP patient.

Study design

This prospective, observational study will collect pelvic floor function and anatomy measurements of 40 POP patients and 20 healthy volunteers without symptomatic POP. The participants will undergo pelvic floor muscle function measurements in a single visit to the outpatient clinic of ZGT (location Hengelo) by myofeedback (MAPLe and TMSI) and TPUS. The TPUS measurements also provide ultrasonographic information about the pelvic anatomy. In addition to these measurements, questionnaires will be obtained during this visit as well:

a general questionnaire (similar to previous trials EPPA NL74061.091.20 and FYSIO NL85627.100.23) and the validated PFIQ-7 and PDFI-20 questionnaires.

Study burden and risks

There is a limited burden for patients to participate in this study. The first burden is travelling, all participants need to go to the ZGT-hospital (Hengelo) for the questionnaires, and the TPUS and myofeedback measurements. However, were possible the study measurements will be combined with the regular outpatient clinic visits of the patients. The second and final burden of this research is based on filling in questionnaires on general health and pelvic floor symptoms.

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

To be eligible to participate in this study, a subject must meet the following criteria:
o Good knowledge of Dutch language
o Women >=18 years of age
o Signed informed consent

Additional inclusion criteria for the different groups:
- Successful pessary fitting (*happy pessary users*):
o Symptomatic stage >=2 POP on POP-Q (physical examination)
o Continued ring pessary (open or closed/supported) usage for >=3 months
- Unsuccessful pessary fitting (*unhappy pessary users*):
o Symptomatic stage >=2 POP on POP-Q
o Unsuccessful fitting of a ring pessary (open or closed/supported): dropping out of the pessary within 7 days or discontinuation due to uncomfortable fit.
- Healthy volunteers:
o Parous (at least 1 vaginal delivery)

Exclusion criteria

Previous prolapse surgery

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL
Recruitment status: Pending

Start date (anticipated):	01-12-2024
Enrollment:	60
Type:	Anticipated

Medical products/devices used

Generic name:	Philips EPIQ7 ultrasound system + Novuqare MAPLe system + TMSi SAGA system with V-Probe
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	11-11-2024
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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	NL87579.100.24