Evaluation of pessary placement on the anatomy of the pelvic organs in patients with pelvic organ prolapse using imaging techniques

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This protocol describes a framework that will be used to create multiple studies, which are based on the secondary objectives. The outcomes of the studies together will provide more insight in the primary objective. Primary Objective: Investigate...

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

Summary

ID

NL-OMON52584

Source
ToetsingOnline

Brief title
EPPA: Evaluation of Pessary Placement on the Anatomy of the pelvic organs

Condition

- Uterine, pelvic and broad ligament disorders

Synonym
Prolapse - pelvic floor dysfunction

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Twente

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Fitting, Magnetic Resonance Imaging (MRI), Pelvic organ prolapse, Pessary

Outcome measures

Primary outcome

In general, the main study endpoints are parameters about the position and shape of the pelvic organs that are associated with successful pessary fitting. Both absolute parameter values and changes in these parameters between the scans with and without pessary will be evaluated. For each study specific parameters will be described.

Secondary outcome

The secondary study endpoints are:

- Parameters which are associated with (a change of) the position and shape of the pelvic organs due to insertion of a pessary in successful pessary fitting, measured using several imaging techniques.
- Position and orientation of the pessary in successful pessary fitting.
- Influence of the moment of the day on the position of the pelvic organs.
- Correlation between the position and orientation of the pessary and anatomical aspects of the levator ani muscle.
- Differences in parameters between patients with successful (i.e. continuation of pessary use for >= 3 months) and unsuccessful pessary fitting.

These parameters will be investigated in the different studies described in

this framework.

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, in 56% of the cases complications occur and the success rates after 1 year are only between 50 and 73%. 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. Therefore, it is needed to investigate the position of a pessary and the influence of a pessary on the pelvic organs to gain more insight in factors associated with successful pessary fitting.
Imaging techniques can be used to evaluate the position of a pessary. Magnetic resonance imaging (MRI) is an imaging technique in which three dimensional imaging of multiple compartments is possible. The additional value of the use of upright MRI is that pessary fitting can be evaluated in the position in which the extent of prolapse is significantly larger than in supine position.
There is a large amount of unknowns considering the effect of a pessary on the pelvic organs. 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

This protocol describes a framework that will be used to create multiple studies, which are based on the secondary objectives. The outcomes of the studies together will provide more insight in the primary objective.

Primary Objective:
Investigate the effect of a pessary on the position and shape of the pelvic organs in patients with POP, when pessary fitting is successful (i.e. the patient continues the use of a pessary for >= 3 months).

Secondary Objectives:
- Evaluate which parameters are associated with a change of the position and shape of the pelvic organs due to insertion of a pessary in successful pessary fitting.
- Evaluate the position and orientation of the pessary in successful pessary fitting.
- Evaluate if the parameters measured using upright MRI can be translated to

parameters which can be measured in imaging techniques used in clinical practice.
- Evaluate if the moment of the day, and therefore the moment of scanning, influences the position of the pelvic organs.
- Set a standard of natural descent during the day in women without symptomatic POP, as to compare with women with symptomatic POP with and without the use of a pessary.
- Evaluate if there is a correlation between the position and orientation of the pessary and anatomical aspects of the levator ani muscle.
- Evaluate which parameters differ between patients with successful (i.e. continuation of pessary use for >= 3 months) and unsuccessful pessary fitting.

Study design

This document is a framework from which different studies will be established in different phases. The outcome of studies in one phase can be used as input information for the next phase. Each study is a prospective cohort study in which the position and orientation of the pelvic organs and the pessary will be investigated. Therefore, in each phase the Esaote G-scan Brio 0.25T MRI will be used, in which patients will be scanned in supine as well as in upright position. Additionally, in some of the phases other imaging techniques such as the Siemens Magnetom Aera 1.5T MRI may be used.

Study burden and risks

In the first study the patients have to visit the University of Twente for two days, one day with the pessary inserted and one day without. On both days they will be scanned three times. In study 1B controls (mostly employees of the University of Twente) will be scanned three times during one day. Those women can work in between, and therefore the extend of burden will be restricted as much as possible. In the other studies only one visit is needed. The patient is not allowed to drink 60 minutes before the start of the scanning procedure and needs to void before the start of the scanning procedure.
During the scanning procedure the patient needs to lie or stand still. In upright position, some people may experience some dizziness because of this. To prevent this, the patient is encouraged to move her toes between the different scans. If dizziness is noticed, the scan will be aborted immediately and the participant is turned back to the horizontal position. The risks associated with MRI are negligible.

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

General:
Signed informed consent

Patients:
Symptomatic pelvic organ prolapse
Pelvic organ prolapse quantification stage 2 or higher
Patient underwent a pessary fitting trial by a gynecologist

Exclusion criteria

General:
Inability to stand for 20 minutes without assistance
Not eligible for MRI, in response to the MRI safety checklist

Controls:
Symptoms related to POP or incontinence (in history)

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	18-02-2021
Enrollment:	105
Type:	Actual

Ethics review

Approved WMO Date:	27-10-2020
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	02-02-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	14-04-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	20-07-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO	

Date:	13-09-2021
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	03-10-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	20-12-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL74061.091.20