Evaluation of Gellhorn pessary on the anatomy of the pelvic floor and the pelvic organs in patients with pelvic organ prolapse using upright MRI

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The primary objective is to evaluate the supporting mechanism of the pelvic floor for a Gellhorn pessary in patients with pelvic organ prolapse immediately after insertion and one week after insertion of the Gellhorn pessary.Secondary Objectives: •...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON57306

Source
ToetsingOnline

Brief title
Gellhorn study

Condition

- Other condition

Synonym
Pelvic Organ Prolapse - Organ descent

Health condition

bekkengynaecologie

Research involving

Human

Sponsors and support

Primary sponsor: Multi-Modality Medical Imaging
Source(s) of monetary or material Support: NWO-OTP project FIT-UP

Intervention

Keyword: Gellhorn, Pelvic Organ Prolapse, Pessary, Upright Magnetic Resonance Imaging

Outcome measures

Primary outcome

The supporting mechanism of the pelvic floor for a Gellhorn pessary

Secondary outcome

* Parameters which are associated with (a change of) the position and shape of

the pelvic organs due to insertion of a Gellhorn pessary

* Position and orientation of the Gellhorn pessary in successful pessary

fitting.

* Translation of parameters measured using upright MRI to parameters which can

be measured in imaging techniques used in clinical practice

* Differences in Gellhorn pessary position between the moment after insertion

and after one week of pessary wearing

* Correlation between the position and orientation of the pessary and

anatomical aspects of the levator ani muscle

- Correlation between the position and orientation of the pessary and

anatomical aspects of the levator ani muscle

- Correlation between the position and orientation of the pessary and

symptomatic improvement

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% [1]. 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% [17]-[19]. 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 [13], [14], [20], [21]. Therefore, from 2022 to 2024 our group executed the EPPA study (NL74061.091.20), were we included healthy controls, patients with successful ring pessary fitting and use and patient with ring pessary dislodgement. We obtained valuable new insights on the position of a ring pessary in the pelvis and on its support mechanism. Several peer reviewed papers have been published using the EPPA data, and an additional three more papers are in preparation or under submission.
The majority of the 29 patients in our *unhappy pessary group*(patients whom discontinued ring pessary use, mainly due to ring drop-out) did continue with a pessary, but from a different type. Specifically the Gellhorn pessary.

It is needed to investigate the position, support and working mechanism of this Gellhorn pessary and its influence on the pelvic organs to gain more insight in the variety of pelvic pessary support mechanisms and the 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 [26].
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

The primary objective is to evaluate the supporting mechanism of the pelvic floor for a Gellhorn pessary in patients with pelvic organ prolapse immediately after insertion and one week after insertion of the Gellhorn pessary.

Secondary Objectives:
• Evaluate which parameters are associated with a change of the position and shape of the pelvic organs due to insertion of a Gellhorn pessary in successful pessary fitting.
• Evaluate the position and orientation of the Gellhorn 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 a difference in Gellhorn pessary position between the moment after insertion and one week of pessary wearing.
• Evaluate if there is a correlation between the position and orientation of the pessary and anatomical aspects of the levator ani muscle.
- Evaluate if there is a correlation between the position and orientation of the pessary and anatomical aspects of the levator ani muscle

Study design

A prospective cohort study in which the participants will undergo upright and supine MRI in two visits: (1) without the pessary and immediately after Gellhorn pessary insertion and (2) one week after Gellhorn pessary insertion. In addition, the following questionnaires are filled out during the first visit: A general questionnaire (as previously used in the EPPA study), PFDI-20 and a pessary questionnaire. Before the first MR scan, the POP-Q measurement will be repeated to define the amount recurring prolapse after pessary removal.

Study burden and risks

This study consists of two scans on the first day and one scan after a week. The scan protocol will be executed at the Esaote 0.25T MRI scanner. First, the participant will be scanned in upright position. Several scans will be acquired for a maximum of 20 minutes. Thereafter, the same scans will be acquired in supine position.

In total, the same protocol will be executed three times: first without the pessary inserted. Approximately 24 hours before the first scan the patient will remove her pessary or have her pessary removed at home or at the hospital. Before the first scan, the POP-Q measurement will be repeated to determine the amount of recurring prolapse after pessary removal. After finishing the scan the Gellhorn pessary is inserted and a second scan is performed in the same manner. One week later the third scan is performed.

During the scanning procedure the participant needs to lie or stand still. In upright position, some people may experience some dizziness because of this. To prevent this, the participant is encouraged to move her toes between the different scans/sequences. 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

The general inclusion criteria are:
- Symptomatic POP
- POP-Q stage >= 2
- Good knowledge of Dutch language
- Signed informed consent
- POP in anterior and/or middle compartment
- Successful Gellhorn pessary treatment for at least 3 months
- Patient is able to remove the pessary herself or willing to visit the ZGT

hospital to let her pessary be removed 24 hours before scanning in case the prolapse is not experienced to the maximal extend immediately after pessary removal.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
* Inability to stand for 25 minutes without assistance
* Not eligible for MRI, in response to the MRI safety checklist
* Abdominal circumference >= 143 cm (jeans size >= 52) or weight >= 200 kg

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	29-01-2025
Enrollment:	30
Type:	Anticipated

Medical products/devices used

Generic name:	Magnetic Resonance Imaging Scan - Esaote
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	13-02-2025

Application type:	First submission
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	NL87774.091.24