

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

Published: 13-02-2025

Last updated: 22-02-2025

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: •...

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|------------------------------|----------------------------|
| <b>Ethical review</b>        | Approved WMO               |
| <b>Status</b>                | Pending                    |
| <b>Health condition type</b> | Other condition            |
| <b>Study type</b>            | 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), where 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

### Public

Selecteer

Drienerlolaan 5  
Enschede 7522 NB  
NL

### Scientific

Selecteer

Drienerlolaan 5  
Enschede 7522 NB  
NL

## 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  $\geq 2$
- 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  $\geq 143$  cm (jeans size  $\geq 52$ ) or weight  $\geq 200$  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 |