

# Silicone compared to polyvinyl chloride ring pessary in the treatment of vaginal prolapse

<b>Submission date</b> 20/08/2025	<b>Recruitment status</b> Recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 01/09/2025	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 26/08/2025	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Pelvic organ prolapse (POP) or vaginal prolapse is when internal organs such as bladder, uterus, or bowel slip down or bulge into the vagina, or in severe cases even beyond the vaginal opening. It is caused by weakness and laxity of local muscles and soft tissues. POP is increasingly common as the person gets older. POP will affect about 405 of women within their lifetime. POP can cause pressure, discomfort, trouble with bladder or bowel function, difficulty with sex, ultimately reducing quality of life.

The ring pessary is a long established and preferred first line treatment for symptomatic POP. It is placed within the vagina to "hold up or hold in" the prolapse, hence restoring the anatomy and relieving symptoms.

The two most commonly used material for the manufacture of the vaginal ring pessary are silicone or polyvinyl chloride (PVC). These materials have different characteristics such as flexibility-rigidity, softness, strength which can influence the clinical performance of the ring pessary.

Pessary performance includes ease and comfort during pessary insertion and removal, bothersome symptoms such as vaginal itching, discharge or bleeding, contact skin breaks, persistent feel of the pessary, spontaneous expulsion and patient satisfaction during pessary use. There is very limited data comparing the performance of a vaginal ring pessary made of silicone or PVC in the treatment of POP.

This study aims to compare pessaries made from silicone or PVC to treat POP in first time users across a broad range of performance outcomes

### Who can participate?

- Women with symptomatic stage 1 to 4 pelvic organ prolapse (POP)
- Mutually agreed upon decision to treat the prolapse using a vaginal ring pessary
- Never used a vaginal pessary before
- Continuing care at the Gynaecology Clinic at University Malaya Medical Centre (UMMC)

Women cannot join if they:

- Have current vaginal wounds / sores / ulcers
- Have a vaginal infection
- Had previous vaginal repair surgery (not including childbirth-related perineal repair)
- Had postmenopausal bleeding in the last six months that has not been investigated
- Had abnormal cervical screening that has not been investigated

What does the study involve?

At recruitment and pessary fitting

Eligible patients will be fully informed about the trial at recruitment and participants will need to provide written consent.

The ring pessary to be used, made from either silicone or PVC will be randomly allocated using a computer program. Neither your doctor nor you are allowed to choose.

Pessary fitting will be conducted according to standard-usual process by your doctor.

Participants will be asked to rate their satisfaction with the pessary fitting process and pain associated with pessary insertion.

At the routine follow-up visit in three months

Participants will be asked to rate their satisfaction with the ring pessary experience and report any symptoms or adverse events they may have experienced since its use. Participation in the study will conclude after this visit, and standard follow-up care will continue to be provided.

If participants present to the clinic or emergency department for an unscheduled visit or to discontinue pessary use prior to the scheduled three-month follow-up, relevant information – complaints, symptoms, and reason for visit – will be retrieved and recorded from their electronic medical record.

What are the possible benefits and risks of participating?

There may or may not be any immediate benefit to the participants. The ring pessary material with better performance may enhance the overall experience with its usage. However, both the pessary materials may perform equally well or equally badly.

Complications directly caused by the study interventions are not anticipated. However, pessary use in general can cause vaginal discharge, vaginal bleeding, pain or discomfort, urinary incontinence or retention, constipation, vaginal skin breaks due to the pressure, or very rarely for the pessary to be trapped needing additional manoeuvres or minor surgery under anaesthesia to deal with the problem.

Participants will be given an advice leaflet about pessary-related care and how to deal with potential pessary-related problems. They will also be provided with the contact number of the investigator for enquiries during working hours for pessary-related issues.

Where is the study run from?

Gynecology Clinic, University Malaya Medical Centre (UMMC) (Malaysia)

When is the study starting and how long is it expected to run for?

May 2025 to December 2026

Who is funding the study?

This study is funded by the 'Bantuan Khas Penyelidikan – Early Career Research Grant (BKPECRG) 2024', Universiti Malaya (Malaysia)

Who is the main contact?

Dr Atiqa binti Abu Bakar, [atiqa.bakar@ummc.edu.my](mailto:atiqa.bakar@ummc.edu.my)

Dr Farah binti Mohd Faiz Gan, [farahgan@um.edu.my](mailto:farahgan@um.edu.my)

Dr Maherah binti Kamarudin, [maherah@um.edu.my](mailto:maherah@um.edu.my)

Professor Dr Tan Peng Chiong, [tanpengchiong@yahoo.com](mailto:tanpengchiong@yahoo.com)

## Contact information

### Type(s)

Public, Scientific, Principal investigator

### Contact name

Dr Atiqa Abu Bakar

### ORCID ID

<https://orcid.org/0009-0003-0441-6679>

### Contact details

Department of Obstetrics and Gynecology

Universiti Malaya Medical Centre

Jalan Profesor Diraja Ungku Aziz

Seksyen 13

Kuala Lumpur

Malaysia

50603

+60 19-5188154

[atiqa.bakar@ummc.edu.my](mailto:atiqa.bakar@ummc.edu.my)

### Type(s)

Public, Scientific, Principal investigator

### Contact name

Dr Farah Mohd Faiz Gan

### ORCID ID

<https://orcid.org/0000-0001-5094-6169>

### Contact details

Department of Obstetrics and Gynecology

Universiti Malaya Medical Centre

Jalan Profesor Diraja Ungku Aziz

Seksyen 13

Kuala Lumpur

Malaysia

59100  
+60176345907  
farahgan@um.edu.my

**Type(s)**

Public, Scientific

**Contact name**

Dr Maherah Kamarudin

**Contact details**

Department of Obstetrics and Gynecology  
Universiti Malaya Medical Centre  
Jalan Profesor Diraja Ungku Aziz  
Seksyen 13  
Kuala Lumpur  
Malaysia  
59100  
+60127440731  
maherah@um.edu.my

**Type(s)**

Public, Scientific

**Contact name**

Prof Dr Tan Peng Chiong

**Contact details**

Department of Obstetrics and Gynecology  
Universiti Malaya Medical Centre  
Jalan Profesor Diraja Ungku Aziz  
Seksyen 13  
Kuala Lumpur  
Malaysia  
59100  
+60123052970  
tanpengchiong@yahoo.com

## **Additional identifiers**

**Clinical Trials Information System (CTIS)**

Nil known

**Protocol serial number**

Nil known

## **Study information**

**Scientific Title**

Silicone vs polyvinyl chloride (PVC) ring pessary for pelvic organ prolapse: a randomised controlled trial

## **Acronym**

SiPVC-PoP

## **Study objectives**

The silicone ring pessary will increase participants' satisfaction with the fitting process after successful fitting and participants' satisfaction with pessary use at 3 months follow up

## **Ethics approval required**

Ethics approval required

## **Ethics approval(s)**

approved 08/08/2025, Universiti Malaya Medical Centre - Medical Research Ethics Committee (UMMC-MREC) (Level 3 Menara Utama Universiti Malaya Medical Centre Lembah Pantai, Kuala Lumpur, 59100, Malaysia; +60 03-79493209; ummc-mrec@ummc.edu.my), ref: 202568-15157

## **Study design**

Parallel-group randomized controlled trial

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Treatment of patients with pelvic organ prolapse using vaginal ring pessary

## **Interventions**

### **Recruitment**

Patient recruitment will take place in the Gynaecology Clinic of Universiti Malaya Medical Centre (UMMC). The Eligibility Assessment Form containing study inclusion and exclusion criteria will be used to screen patients. Patients who fulfil study criteria will be provided the Patient Information Sheet and counselled with regards to trial participation. Queries about the study will be invited and answered by the recruiting investigator. Written informed consent will be obtained from all participants. Their baseline characteristics including the completed Prolapse-Quality of Life (P-QOL) questionnaire will be transcribed onto the Case Report Form.

### **Randomisation**

Participants will be randomised to receiving either Silicone ring pessary or PVC ring pessary. Randomisation sequence will be generated using an online generator in blocks of 4 or 8, following a 1 to 1 ratio, by a co-investigator who will not be involved in the recruitment process. Allocation will be sealed within a numbered opaque envelope. Randomisation will be implemented using strict sequential allocation and opening of the lowest-numbered sealed envelope remaining to the latest recruit.

### **Ring pessary fitting**

A digital vaginal examination will be performed - the inserted middle fingertip will be placed

behind the cervix and the index fingertip against the pubic notch. After withdrawing the fingers, the distance between the tips of these fingers will be matched onto a ring pessary to select the initial pessary for fitting. The ring pessary will be compressed to reduce its width and introduced into the vagina. Once more than half of the compressed ring has been inserted, it will be gradually released as it is further inserted. The pessary will usually end up in the correct position. If adjustment is needed, it may be pushed upwards with the index finger to place the anterior edge behind the symphysis pubis, and the posterior edge in the posterior vaginal fornix.

The pessary should be retained in place on standing, coughing, Valsalva, and upon movement. The woman will be asked regarding any pain or discomfort, whether she is able to void, and if there is any de novo or worsening of incontinence before she leaves the clinic. If removal is needed, an index finger will be hooked around the anterior leading edge of the pessary ring to bring it down to the introitus, then eased out of the vagina. If the initial pessary fitting is unsuccessful, subsequent attempts will be with a ring size to be decided by the care provider. The number of fitting attempts before abandonment or change to a pessary of a different make will be at the sole discretion of the care provider.

At the end of the clinic visit, participants' satisfaction with the pessary fitting process, pain score associated with the ring insertion, whether or not fitting was successful, make of the successfully-fitted pessary, number of fitting attempts, ring diameter of the successfully-fitted pessary, and ease of insertion by the provider will be assessed and recorded onto the Case Report Form.

Participants will be given an advise leaflet about pessary care and provided with the contact number of an investigator for pessary-related issues during working hours. They will be advised to attend the Emergency Department for urgent care (e.g., urinary retention, severe pain, etc) out of hours.

#### Follow up

Participants will be asked to return for their standard follow-up in three months. During this visit, participants' satisfaction with their experience of pessary use, pessary discontinuation, make of the pessary in use, presence of any adverse interim symptoms, and number of unscheduled pessary-related visits will be recorded.

During the pessary change, the pain score associated with pessary removal, ease of removal (by provider), pessary condition, vulval and vaginal assessment after pessary removal (speculum), major harms (if present), stage of Pelvic Organ Prolapse, pain score associated pessary re-insertion, ease of insertion (by provider), and the make and diameter of the re-inserted pessary. Participants will be asked to complete the P-QOL questionnaire and whether they would agree to recommend their allocated ring pessary to a friend.

If a participants presented for an unscheduled visit or discontinue pessary use prior to the three month follow up review, data will be retrieved from the participants' electronic medical record and the complaints, symptoms, or reason for visit recorded.

Study participation ends at the three months follow up visit and follow-on standard care will be offered.

#### **Intervention Type**

Device

#### **Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Silicone ring pessary, PVC ring pessary

**Primary outcome(s)**

1. Participants' satisfaction with the pessary fitting process (after successful fitting, at end of clinic visit), using an 11-point 0-10 Numeric Rating Scale (NRS) [higher score, greater satisfaction] (by participants)
2. Participants' satisfaction with pessary use, using an 11-point 0-10 NRS [higher score, greater satisfaction] (at three months follow up) (by participants)

**Key secondary outcome(s)**

At the end of clinic visit, record

1. Successful fitting (by provider)
2. Make of successfully-fitted pessary (by provider)
3. Participants' pain score associated with insertion using an 11-point 0-10 NRS [higher score, greater pain] (by participants)
4. Number of fitting attempts (until successful fitting) (by provider)
5. Ease of insertion using an 11-point 0-10 NRS [higher score, greater ease] (by provider)
6. Ring diameter of successfully-fitted pessary (by provider)

At three months follow up, record

7. Pessary discontinuation and reason (by participants)
8. Pessary make in use (by provider)
9. Adverse interim symptoms during first three months after pessary insertion using a 4-grade Likert scale (by participants):
  - 9.1. Bothersome vaginal discharge
  - 9.2. Vulva-vaginal itching
  - 9.3. Vaginal bleeding
  - 9.4. Pessary dislodged
  - 9.5. I can feel the pessary
  - 9.6. Pessary discomfort
10. Number of unscheduled pessary-related visits (by participants)
11. Prolapse Quality of Life (P-QOL) questionnaire (by participants)
12. Recommends allocated (PVC or silicone) ring pessary to a friend, using a 5-grade Likert scale (by participants)
13. Pessary removal
  - 13.1. Participants' pain score associated with removal using 0–10 NRS [higher score, greater pain] (by participants)
  - 13.2. Ease of removal using 0–10 NRS [higher score, greater ease] (by provider)
  - 13.3. Pessary condition: Reusable / Needs replacement (by provider)
14. Vulval and vaginal (speculum) examination after pessary removal (by provider)
  - 14.1. Vaginal mucosal erosion / ulceration
  - 14.2. Vaginal mucopurulent discharge
  - 14.3. Vaginal foul / offensive odour
15. Major harms, if present (by provider)
  - 15.1. Pessary retention requiring surgical release under anaesthesia
  - 15.2. Lower genital laceration requiring surgical repair under anaesthesia
16. Stage of Pelvic Organ Prolapse using POP-Q (Pelvic Organ Prolapse Quantification) system (by provider)

- 17. Pessary insertion
  - 17.1. Participants' pain score associated with insertion using 0–10 NRS (by participants)
  - 17.2. Ease of insertion using 0–10 NRS (by provider)
- 18. Pessary reinserted (by provider)
  - 18.1. Make (Silicone / PVC / Other pessary)
  - 18.2. Ring diameter

**Completion date**

31/12/2026

## Eligibility

**Key inclusion criteria**

1. Symptomatic stage 1 to Stage 4 POP (using the POP-Q system assessment)
2. Shared decision for a vaginal ring pessary to treat POP
3. Never before used a vaginal pessary for POP treatment

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

18 years

**Upper age limit**

75 years

**Sex**

Female

**Key exclusion criteria**

1. Existing vaginal or vulvar lacerations / ulcers
2. Vaginal infection
3. Previous vaginal repair surgery (not including childbirth-related perineal repair)
4. Postmenopausal bleeding in the last 6 months (if not fully investigated)
5. Abnormal cervical screening (if not fully investigated)

**Date of first enrolment**

15/09/2025

**Date of final enrolment**

15/09/2026

## Locations

## Countries of recruitment

Malaysia

## Study participating centre

**Gynecology Clinic Universiti Malaya Medical Centre (UMMC)**

Women and Children Health Complex, Lembah Pantai

Kuala Lumpur

Malaysia

59100

## Sponsor information

### Organisation

Early Career Research Grant (ECRG) Bahagian Pengurusan Geran Penyelidikan

## Funder(s)

### Funder type

University/education

### Funder Name

Universiti Malaya

### Alternative Name(s)

University of Malaya, University Malaya, Malayan University, King Edward VII College of Medicine, Raffles College, University of Malaya in Singapore, , , , UM

### Funding Body Type

Government organisation

### Funding Body Subtype

Universities (academic only)

### Location

Malaysia

## Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available subject to ethics board approval upon request from Dr Atiqa Abu Bakar [atiqa.bakar@ummc.edu.my](mailto:atiqa.bakar@ummc.edu.my) or Dr Farah binti Mohd Faiz Gan [farah.faizg@ummc.edu.my](mailto:farah.faizg@ummc.edu.my)

Data: Summary data and de-identified participants information

Data will be available 3 months after the end date and remains available for 7 years

Data will be shared for academic purposes only upon request

Data will be made available via email request

Informed consents will be obtained from all participants

All data will be de-identified so that participants remain anonymous.

No ethical or legal restrictions

### **IPD sharing plan summary**

Available on request