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

Submission date
20/08/2025

Recruitment status
Not yet recruiting

Registration date
01/09/2025

Overall study status
Ongoing

Last Edited
26/08/2025

Condition category
Urological and Genital Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] 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)

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
To follow

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 release 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, Vasalva, 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 unsceduled 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

Pharmaceutical study type(s)
Not Applicable

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Silicone ring pessary, PVC ring pessary

Primary outcome measure
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)

Secondary outcome measures
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

Overall study start date
31/05/2024

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

Age group
Mixed

Lower age limit
18 Years

Upper age limit
75 Years

Sex

Female

Target number of participants
Total 200 participants

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
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Sponsor information

Organisation
Early Career Research Grant (ECRG) Bahagian Pengurusan Geran Penyelidikan

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Sponsor type
University/education

Website
https://umresearch.um.edu.my/research-grant/

Funder(s)

Funder type
University/education

Funder Name
Universiti Malaya

Alternative Name(s)
University of Malaya, University Malaya, Malayan University, UM

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Malaysia

Results and Publications

Publication and dissemination plan
Planned publication in a high impact peer-reviewed journal

Intention to publish date
31/12/2027

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 or Dr Farah binti Mohd Faiz Gan 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