

Comparing pain during pessary change: sitting position versus side-lying position

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		<input checked="" type="checkbox"/> Protocol
Registration date 20/04/2026	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 20/04/2026	Condition category 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 is a common condition where the womb, bladder, bowel, or vaginal walls drop down and cause symptoms such as a vaginal lump, discomfort, or pressure. Many women are treated using a vaginal pessary, which is a removable silicone or PVC device placed inside the vagina to support the pelvic organs. Pessaries need regular removal and replacement in clinic. This procedure can cause discomfort or pain for some women. The usual position for pessary change is the lithotomy position (lying on the back with legs supported), but some women may find the left-lateral position (lying on the left side) more comfortable. This study aims to compare pain and comfort during pessary replacement between these two positions.

Who can participate?

Women aged 18 years and above with pelvic organ prolapse who are already using a ring pessary and attending clinic for routine pessary replacement may be invited to take part. Women who cannot safely lie in either study position, have active vaginal infection, significant bleeding, or are having a pessary inserted for the first time will not be included.

What does the study involve?

Participants who agree to join the study will be randomly assigned (like flipping a coin) to have their pessary changed in either the lithotomy position or the left-lateral position. The pessary change will be carried out by trained doctors in the clinic using standard practice. Participants will be asked to rate their pain using a simple 0 to 10 pain scale after the procedure. They may also be asked about comfort and satisfaction. The doctor performing the procedure will record ease of insertion/removal and procedure time. If needed for comfort or safety, the position may be changed during the procedure.

What are the possible benefits and risks of participating?

Participants may or may not personally benefit from taking part. Some women may find one position more comfortable than the other. Information from this study may help improve future care for women needing pessary treatment. Risks are low and similar to standard pessary care, including temporary discomfort, pain, light bleeding, or minor vaginal irritation during pessary removal or reinsertion.

Where is the study run from?

The study is run from the Department of Obstetrics and Gynaecology, Pusat Perubatan Universiti Malaya (University Malaya Medical Centre), Kuala Lumpur, Malaysia.

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

April 2026 to December 2026.

Who is funding the study?

Pusat Perubatan Universiti Malaya (University Malaya Medical Centre), Kuala Lumpur, Malaysia.

Who is the main contact?

Principal Investigator: Dr Adli Hakimi Bin Zulkifli, adlihakimi@ummc.edu.my

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Study information

Scientific Title

A randomized trial comparing pain levels during pessary replacement in lithotomy versus left-lateral position among women with pelvic organ prolapse

Study objectives

Primary Aim:

To compare pain levels during pessary removal and replacement between lithotomy and left-lateral positions among women with pelvic organ prolapse.

Secondary Objectives:

1. To compare patient-reported comfort, acceptability, and perceived dignity between the two positions.
2. To evaluate clinician-reported ease of pessary removal and insertion in each position.
3. To compare procedural characteristics, including duration and need for repositioning or rescue measures.
4. To assess the incidence of procedure-related adverse events (e.g. vaginal trauma, bleeding, or discomfort).

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 15/02/2026, Medical Research Ethics Committee, University of Malaya Medical Centre (Pusat Perubatan Universiti Malaya (Universiti Malaya Medical Center), Lembah Pantai, Kuala Lumpur, 59100, Malaysia; +60379494422; ummc-mrec@ummc.edu.my), ref: MREC ID NO: 20251211-15997

Primary study design

Interventional

Allocation

Randomized controlled trial

Masking

Open (masking not used)

Control

Active

Assignment

Parallel

Purpose

Health services research, Supportive care

Study type(s)

Health condition(s) or problem(s) studied

Pain and procedural comfort during pessary replacement in women with pelvic organ prolapse.

Interventions

This study is a randomized, parallel-group controlled trial comparing two active interventions: lithotomy position (control) and left-lateral position (intervention) during routine pessary removal and replacement in women with pelvic organ prolapse.

Eligible participants will be identified during scheduled gynaecology clinic visits and recruited following informed consent. Participants will be randomly assigned in a 1:1 ratio to either lithotomy or left-lateral position using a sealed opaque envelope method to ensure allocation concealment.

All procedures will be performed by trained obstetrics and gynaecology clinicians following a standardized technique for pessary removal and reinsertion using the participant's usual ring pessary and appropriate lubrication. The intervention consists of positioning the participant either in the lithotomy or left-lateral position during the procedure. No change in pessary type or size will be made.

The primary outcome is patient-reported pain measured using a 0–10 Numerical Rating Scale (NRS) immediately after pessary removal and at 5 minutes post-procedure. Secondary outcomes include patient-reported comfort, acceptability and dignity, clinician-reported ease of insertion, procedure duration, need for repositioning or rescue measures, and occurrence of adverse events such as vaginal trauma or bleeding.

Participants will remain in their assigned position throughout the procedure unless a rescue change of position is required for safety, excessive discomfort, or procedural difficulty. All analyses will be conducted according to the initial randomized allocation.

Intervention Type

Procedure/Surgery

Primary outcome(s)

1. Pain score during pessary removal measured using a 0–10 Numerical Rating Scale (NRS) at immediately post-removal

Key secondary outcome(s)

1. Pain intensity during ring pessary insertion measured using a 0–10 Numerical Rating Scale (NRS) at immediately post-removal

2. Clinician-rated ease of ring pessary removal and insertion measured using a 5-point Likert scale at immediately after completion of the procedure

3. Procedure time at commencement of pessary removal to completion of pessary reinsertion measured using stopwatch in minutes at during the procedure

4. Patient satisfaction measured using a 5-point Likert scale at immediately after completion of the procedure

5. Need for re-insertion, readjustment (rescue), or unscheduled pessary review, within 4 weeks after the procedure measured using data collected clinical case record documentation at one time point

Completion date

31/12/2026

Eligibility

Key inclusion criteria

1. Women aged 18 years and above
2. Diagnosed with pelvic organ prolapse (POP)
3. Currently using a ring pessary for management of POP
4. Scheduled for routine pessary removal and replacement at the gynaecology clinic
5. Able to lie in both lithotomy and left-lateral positions safely
6. Able to understand the study information and provide written informed consent

Healthy volunteers allowed

Yes

Age group

Mixed

Lower age limit

18 years

Upper age limit

70 years

Sex

Female

Total final enrolment

0

Key exclusion criteria

1. Women undergoing first-time pessary insertion
2. Presence of active vaginal infection (e.g. vaginitis, ulceration requiring treatment)
3. History of postmenopausal bleeding within the past 6 months
4. Inability to safely tolerate lithotomy or left-lateral position (e.g. severe hip or knee osteoarthritis, recent lower limb or pelvic surgery, significant spinal deformity, severe chronic back pain, or marked mobility limitation)
5. Acute vaginal complications requiring urgent management (e.g. significant bleeding, severe pain, or suspected injury)
6. Cognitive impairment or language barrier preventing understanding of the study or reliable pain scoring
7. Declines or unable to provide informed consent

Date of first enrolment

16/04/2026

Date of final enrolment

31/08/2026

Locations**Countries of recruitment**

Malaysia

Study participating centre

Pusat Perubatan Universiti Malaya (Universiti Malaya Medical Center)

Lembah Pantai, 59100 Kuala Lumpur, Federal Territory of Kuala Lumpur

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Sponsor information**Organisation**

University of Malaya

ROR

<https://ror.org/00rzspn62>

Funder(s)

Funder type

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

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other files	version 3	01/02/2026	17/04/2026	No	No
Other files	version 1.0	11/12/2025	17/04/2026	No	No
Participant information sheet	version 3.0	01/02/2026	17/04/2026	No	Yes
Protocol file	version 5	09/02/2026	17/04/2026	No	No