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UNIVERSITY OF MALAYA MEDICAL CENTRE

RESEARCH PROTOCOL

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TITLE OF RESEARCH PROPOSAL

A Randomized Trial Comparing Pain Levels During Pessary Replacement in Lithotomy versus Left-Lateral Position Among Women with Pelvic Organ Prolapse

KEY WORDS

Ring pessary; Pelvic Organ Prolapse; Left lateral; Lithotomy

BACKGROUND/ JUSTIFICATION

Pelvic organ prolapse (POP) is commonly managed with vaginal pessaries, which require regular replacement in outpatient settings. Although pessary care is considered a minor procedure, many women experience discomfort or pain during pessary replacement, which may affect adherence to long-term conservative management. Traditionally, pessary changes are performed in the dorsal lithotomy position; however, pelvic examination practices vary widely, and alternative positions such as the left lateral (Sims) position are frequently used, particularly in women with prolapse (Amias, 1987).

Evidence from randomized and observational studies demonstrates that alternative pelvic examination positions are associated with reduced pain, anxiety, and perceived vulnerability without compromising examination quality (Seymore et al., 1986; Seehusen et al., 2006). The left lateral position has also been validated for POP assessment, showing high inter-observer reliability and strong correlation with lithotomy findings (Digesu et al., 2009). Additional studies suggest practical advantages of lateral positioning, particularly in women with obesity or limited mobility (Breitkopf, 2021; Selçuk et al., 2014). Despite this, no randomized trial has specifically compared pain during pessary replacement between lithotomy and left lateral positions.

OBJECTIVES & EXPECTED OUTCOMES

Objectives:
The major aim of the research is to determine the pain levels during pessary replacement in the lithotomy or the left-lateral position. The secondary goals will be to determine patient preference and satisfaction with the two positions, how the perceived dignity is influenced by the procedure, and to establish how easily a pessary can be removed and inserted in each position, as rated by a clinician.

Expected outcomes:

Primary Outcome: Pain intensity during the ring pessary removal
Secondary Outcome:

1. Pain intensity during the ring pessary insertion
2. Procedure time
3. Ease of clinician for removal and insertion
4. Patient's satisfaction
5. Determine whether any re-insertion, readjustment (rescue), or unscheduled pessary review was required

METHODOLOGY

Study design
A randomized clinical trial with two arms:
Group 1: Lithotomy position
Group 2: Left-lateral position

Inclusion criteria

1. Attending clinic for ring pessary change or review
2. POP managed using PVC ring pessary (most common in our centre)
3. Able to lie in lithotomy or left lateral position

Exclusion criteria

1. First time insertion of vaginal pessary
2. Vaginal infection
3. Post menopausal bleeding in the last 6 months (if not investigated)
4. Abnormal cervical cytology / histology
5. Women with medical, musculoskeletal, or neurological conditions that prevent safe positioning in either the lithotomy or left-lateral position, such as severe hip or knee osteoarthritis, recent lower-limb or pelvic surgery, significant spinal deformity, severe chronic back pain, or mobility limitations that preclude positioning required for the study.

Discontinuation criteria

A participant will be withdrawn from the study if any of the following occur:

1. The participant chooses to withdraw from the study or requests that the procedure be stopped at any time, for any reason
2. The participant experiences significant pain, discomfort, distress, or anxiety during the procedure despite appropriate measures, including a rescue procedure
3. The procedure cannot be completed safely or reasonably in the allocated or alternative position
4. An adverse event occurs, such as bleeding or injury, that requires termination of the procedure
5. The care provider judges that continuing the procedure may pose a risk to the participant or is not in the participant's best interest

Type and size of pessary used

This study involves women who are already using a ring pessary as part of their routine care. Only ring pessaries will be included. Participants will continue using the same type and size of ring pessary that they were previously prescribed.

Decision on pessary type and size

The type and size of ring pessary are determined by the treating clinician prior to study enrolment as part of standard clinical care. Study participation does not influence the choice of pessary type or size.

Pessary change and replacement

This study involves routine ring pessary replacement, typically performed every 4–6 months. Participation in the study does not require any change in pessary type or size. No participant will be asked to switch to a different pessary type or size because of the study.

Methodology

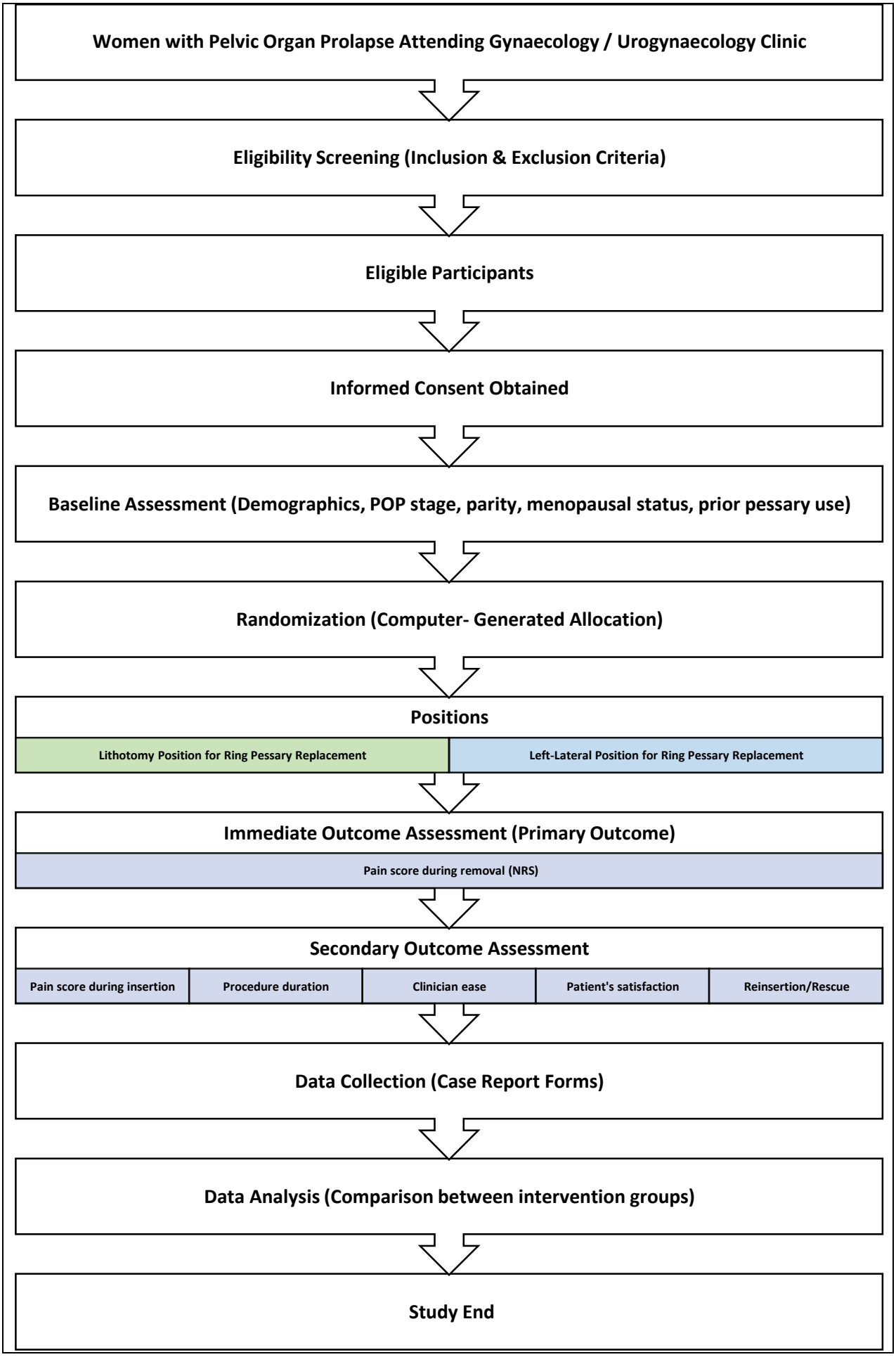
6. All care providers involved in this study will be medical officers, registrars, or consultants in Obstetrics and Gynaecology with prior experience in ring pessary replacement. No nurses or non-medical personnel will perform the pessary replacement.
7. Before study initiation, a brief standardisation session will be conducted to ensure consistency of technique. This session will include a review of the study protocol, standard steps for pessary removal and reinsertion, consistent use of lubricant, and standard patient instructions. The procedure will be identical in both study arms, with the only difference being patient positioning. No additional analgesia or local anaesthetic will be used.
8. Patient's suitability will be assessed via EMR and completion of EAF, based on inclusion and exclusion criteria
9. Patient will be given Patient Information Sheet (PIS).
10. After consent, participants' demographic and clinical characteristics will be recorded using the Case Report Form (CRF).
11. Patient will be randomized (1:1) into Left Lateral or Lithotomy groups using computer-generated random numbers (https://www.sealedenvelope.com/simple-randomiser/v1/lists).
12. Participants will be asked to rate their pain intensity during the ring pessary removal and reinsertion using an 11-point Numerical Rating Scale (NRS), where 0 represents "no pain" and 10 represents "the worst pain imaginable."
13. The care provider performing the pessary removal will rate the ease of insertion using a 5-point Likert scale, where 1 = very easy, 2 = easy, 3 = neutral, 4 = difficult, and 5 = very difficult.
14. Vulva will be inspected for any bleeding, erythema, or laceration. A speculum examination will then be performed to assess the vaginal walls for ulceration, new lacerations, or bleeding.
15. Rescue procedures will be allowed in both study arms. Participants may be converted from the allocated position to the alternative position if the procedure cannot be safely or reasonably completed or if significant discomfort occurs. The decision to initiate a rescue procedure may be made by either the participant or the care provider, with participant comfort and safety always taking priority.
16. All rescue procedures, including the direction and reason for crossover, will be recorded. Data will be analyzed based on the initial randomized allocation.
17. Timing will begin at the point of glove insertion into the vagina ("glove on") and end when the new pessary is fully seated
18. Data will be analyzed using SPSS. Data cleaning will include checks for completeness, missing data, outliers, and assessment of normality for continuous variables.

    Analyses will be conducted based on initial randomized allocation (intention-to-treat).
    Primary outcome: Mean NRS comparison between lithotomy vs left-lateral using an independent two-sample t-test
    Secondary outcomes:
    a. NRS during insertion/removal: t-test
    b. Procedure time (seconds): t-test
    c. Clinician ease (5-point Likert): Mann–Whitney U test.
    d. Patient acceptability (PAQ total score): independent two-sample t-test

e. Rescue switch (yes/no): Chi-square test
f. Adverse events (yes/no): Chi-square test

Statistical significance will be set at $p < 0.05$

Schematic Diagram


Women with Pelvic Organ Prolapse Attending Gynaecology / Urogynaecology Clinic
Eligibility Screening (Inclusion & Exclusion Criteria)
Eligible Participants
Informed Consent Obtained
Baseline Assessment (Demographics, POP stage, parity, menopausal status, prior pessary use)
Randomization (Computer- Generated Allocation)
Positions
Lithotomy Position for Ring Pessary Replacement
Left-Lateral Position for Ring Pessary Replacement
Immediate Outcome Assessment (Primary Outcome)
Pain score during removal (NRS)
Secondary Outcome Assessment
Pain score during insertion
Procedure duration
Clinician ease
Patient's satisfaction
Reinsertion/Rescue
Data Collection (Case Report Forms)
Data Analysis (Comparison between intervention groups)
Study End

Sample size
The planned sample size for this study is 128 participants. Pain score is the primary outcome measure. Sample size estimation was performed to detect a clinically meaningful difference in mean pain scores between the two examination positions, assuming a mean pain score of 4 in the left lateral position and 6 in the lithotomy position, with a common standard deviation of 4. Using a two-sided significance level (α) of 0.05 and a statistical power of 80%, a minimum of 64 participants was required in each group. To account for an anticipated dropout rate of approximately 10%, six additional participants were added to each group. Therefore, the final target sample size is 128 participants.

Data Analysis
Data will be analyzed using SPSS, ensuring proper checking for normality and missing data handling.

Primary Outcome: Independent two-sample t-test comparing mean NRS between lithotomy vs left-lateral.
Secondary Outcomes:

19. NRS during insertion**:** same approach as primary
20. Procedure time (seconds): t-test
21. Clinician ease (5-point Likert): Mann–Whitney U
22. Patient acceptability (PAQ total score): Independent two-sample T test
23. Rescue switch: Chi square
24. Adverse event: Chi square

Statistical Significance: $p < 0.05$

RESEARCH DATA

Where will the data be kept? (Please provide details)
All case report form will be printed and filed up, and will be stored in a locked drawer

Who will have access to the research data?
Only the investigators. Anonymised (where individuals cannot be identified) trial data may be released to other researchers in the future as permitted by the Ethics committee.

How long will the data be kept? (suggestion: at least 7 years)
It will be kept for 10 years.

BUDGET / FINANCIAL SUPPORT (IF APPLICABLE):

No	Budget Detail	Amount (RM)
1.	-	-
2.		
3.		

Grand Total	

GANTT CHART

ACTIVITIES \ YEAR	2026								
	4	5	6	7	8	9	10	11	12
1. Ethics application & approval	■								
2. Questionnaire validation & Build up the open source online questionnaires	■								
3. Pilot study	■								
4. Data collection	■	■	■	■	■				
5. Data entry & analysis				■	■	■			
6. Manuscript writing						■	■		
7. Submission for publication							■	■	■
8. Research progress report & presentation									■

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POTENTIAL IMPACT

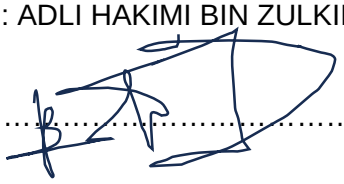
This study is important as to our best knowledge there is lack of data within a clinical trial context on the position during ring pessary change may affect the patient's perception of pain and integrity, and subsequently may change our standard practise.

3. Please state whether you have submitted this research proposal for funding, now or before
   - ☐ Yes: If Yes, which grant? _____
   - ✓ No

This proposal will be kept strictly private and confidential. It will not be shared with anyone without your prior approval.

Name of Researcher (CAPITAL): ADLI HAKIMI BIN ZULKIFLI

Signature of Researcher: ……



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