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Removal technique of ring pessary in pelvic organ prolapse

Submission date
17/01/2025

Recruitment status
No longer recruiting

Registration date
20/01/2025

Overall study status
Completed

Last Edited
20/01/2025

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
The ring pessary commonly available and used in Malaysia is made from polyvinyl chloride (PVC) and is relatively stiff and inflexible. The PVC ring pessary provides good support for pelvic organ prolapse. Still, it is more challenging to insert and remove as the ring diameter needed is usually bigger than the diameter of the vaginal opening. The vaginal opening is largest when measured from front to back but once into the vaginal canal the biggest dimension is side to side. Removal and insertion of the ring pessary is a tight fit through the vaginal opening in patients with pelvic organ prolapse and can cause some pain. The technique used when removing the ring pessary may influence the severity and perseverance of associated pain. Vaginal pessary is the often first-line management of pelvic organ prolapse and the ring pessary is the commonest type in use. Women using the ring pessary longer term have reported pessary removal to be more painful than insertion during their periodic pessary assessment and change. This study investigates whether reducing the pain with a superior pessary removal technique is possible as information on a better technique is unavailable.

Who can participate?
Women attending the Gynaecology Clinic at the University Malaya Medical Centre (UMMC) and fulfil the inclusion criteria of this study:
1. Attended clinic for ring pessary change or review.
2. Mild Stage 1, Stage 2 pelvic or Stage 3 organ prolapse (staging based on the POP-Q system)
3. Using the PVC (polyvinyl chloride) ring pessary

What does the study involve?
This study plans to evaluate if a rotating motion to twist the vaginal PVC ring pessary to a vertical position with the downward and outward pull compared to the standard downward and outward horizontal pull would reduce women’s pain score during ring pessary removal. It will also evaluate any superficial skin abrasion to the vagina, patient satisfaction, and the clinician’s sense of ease of pessary removal with the techniques.

What are the possible benefits and risks of participating?
What are the possible benefits to participants?
There may or may not be any immediate benefits to participants. If found to be effective, the studied pessary removal technique may reduce pain and risk of genital tract trauma.

What are the possible disadvantages and risks to participants?
Major complications are not anticipated. The current standard technique of ring pessary removal can occasionally cause minor genital tract injury (bleeding, skin abrasions). The impact of the technique under study on pain and injury is not known. It may increase pain or injury.

Where is the study run from?
Gynaecology Clinic at UMMC, Kuala Lumpur, Malaysia.

When is the study starting and how long is it expected to run for?
January 2024 to January 2026

Who is funding the study?
Department of Obstetrics and Gynaecology, UMMC

Who is the main contact?
Dr Fahazrinizam Bin Mat Desa, Medical Officer, Department of Obstetrics and Gynaecology, 17084696@siswa.um.edu.my, fahazrinizam@gmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Study information

Scientific Title
Removal technique of ring pessary in pelvic organ prolapse: a randomized controlled trial. Comparisation of vertical rotating and standard horizontal traction of PVC ring pessary.

Study objectives

It is hypothesized that after first grasping with the index-middle fingers the infra symphysis pubis portion of the indwelling ring pessary, 1) rotating to vertical the ring pessary in downward and outward traction to remove it, compared to 2) standard removal by downward and outward traction with the ring pessary in the horizontal plane to remove it, will reduce the patient's pain score.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 24/04/2024, Medical Research Ethic Committee of the University Malaya Medical Centre (Lembah Pantai, Kuala Lumpur, 59100, Malaysia; +603 7949 3209; ummc-mrec@ummc.edu.my), ref: 2024219-13422

Primary study design
Interventional

Study design
Parallel-group randomized controlled trial

Study type(s)
Other

Health condition(s) or problem(s) studied
Comparing two techniques for less pain and fewer complications during the removal of a PVC ring pessary in patients with pelvic organ prolapse

Interventions
Patient recruitment will take place in the Gynaecology Clinic of UMMC. Before approaching these women, we will assess for suitability for recruitment into the trial through their Electronic Medical Records (EMR) and the use of the eligibility assessment form (EAF), based on the inclusion and exclusion criteria mentioned above.

Eligible women will be approached and provided with the Patient Information Sheet (PIS) and counselled about trial participation (as described below). Queries about the study are invited and will be answered by the recruiting investigator. Written informed consent will be obtained. Participants' characteristics as per the Case Report Form (CRF) and data will be transcribed thereof.

Participants will be informed that their existing ring pessary will be removed and checked for the need to replace with a new ring pessary or it could be reused after cleaning as standard practice.

Interventions
They will then be randomised to:
(1) Intervention group: after first grasping with the index-middle fingers the infra symphysis pubis portion of the indwelling ring pessary, rotating it vertically the ring pessary in the downward and outward traction to remove

(2) Control group: after first grasping with the index-middle fingers the infra symphysis pubis portion of the indwelling ring pessary, standard removal by downward then outward traction with the ring pessary in the horizontal plane to remove.

Randomisation
The randomisation sequence will be generated online using https://www.sealedenvelope.com /simple-randomiser/v1/lists, 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 opening of the lowest-numbered remaining sealed envelopes to the latest recruit.

Outcomes
After pessary removal, the vulva will be inspected for bleeding and laceration. A speculum examination will be performed to check the vaginal for ulceration, new laceration, and bleeding. Prolapse will be graded using the POP-Q system.

Participants will be asked to rate their pain scores during the ring pessary removal on an 11-point Numerical Rating Scale (NRS), 0 as no pain to 10 as the worst pain imaginable, 1) immediately after removal and 2) 5 minutes after removal. The care provider who inserted the ring pessary will be asked to rate the ease of insertion, also using the 11-point NRS with 0 as the easiest insertion imaginable to 10 as being the worst insertion imaginable. Participants will also be asked using a 5-grade Likert scale response if they would recommend their allocated removal technique to a friend. We will review participants' medical records to check for the need to reinsert or readjust the ring pessary within 4 weeks.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Pain score measured using a 0-10 Numerical Rating Score (NRS) immediately and 5 minutes after pessary removal

Key secondary outcome(s)
1. Ease of removal by the clinician using the allocated insertion technique measured using a 0-10 Numerical Rating Score (NRS) at the end of the procedure
2. Recommendation to a friend of allocated removal technique measured using a 5-grade Likert scale at the end of the procedure
3. Vulva-vaginal bleeding measured using data collected in the participants' medical records at a single timepoint
4. Vaginal laceration at speculum examination measured using data collected in the participants' medical records at a single timepoint
5. Vulvar laceration on visual inspection measured using data collected in the participants' medical records at a single timepoint
6. Pain score measured using a 0-10 Numerical Rating Score (NRS) immediately and 5 minutes after standard pessary reinsertion

Completion date
01/01/2026

Eligibility

Key inclusion criteria
1. Attending clinic for ring pessary change or review
2. Stage 1, Stage 2 or Stage 3 POP (defined as descending not more than 1cm below hymen using the POP-Q technique)
3. POP managed using PVC ring pessary (most common in our centre)

Participant type(s)
Patient, Health professional

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
45 Years

Upper age limit
90 Years

Sex
Female

Key exclusion criteria
1. First-time insertion of vaginal pessary
2. Existing vaginal or vulvar lacerations
3. Vaginal infection
4. Previous vaginal surgery (not including childbirth related perineal repair)
5. Postmenopausal bleeding in the last 6 months (if not investigated)
6. Abnormal cervical cytology / histology (if not investigated)

Date of first enrolment
05/06/2024

Date of final enrolment
25/04/2025

Locations

Countries of recruitment
Malaysia

Study participating centre
Gynaecology Clinic, University Malaya Medical Centre (UMMC)
Lembah Pantai
Kuala Lumpur
Malaysia
59100

Sponsor information

Organisation
University Malaya Medical Centre

ROR
https://ror.org/00vkrxq08

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Department of Medicine, University of Malaya

Alternative Name(s)
Faculty of Medicine - Universiti Malaya, Medicine Department - Faculty of Medicine - Universiti Malaya, medicineumalaya, University of Malaya Faculty of Medicine

Funding Body Type
Government organisation

Funding Body Subtype
Research institutes and centers

Location
Malaysia

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Fahazrinizam Bin Mat Desa, 17084696@siswa.um.edu.my, fahazrinizam@gmail.com

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Participant information sheet	version 1.1	26/01/2024	20/01/2025	No	Yes
Protocol file	version 1.1	26/01/2024	20/01/2025	No	No