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Application of local anaesthetic cream at ring pessary change in vaginal prolapse

Submission date	Recruitment status	[X] Prospectively registered
13/06/2025	Recruiting	[_] Protocol
Registration date	Overall study status	[_] Statistical analysis plan
16/06/2025	Ongoing	[_] Results
Last Edited	Condition category	[_] Individual participant data
16/06/2025	Urological and Genital Diseases	[X] Record updated in last year

Plain English summary of protocol

Background and study aims
About 40% of women will experience ‘something coming down’ the vagina or pelvic organ prolapse (POP) within their lifetime. Ring pessaries inserted into the vagina to support the prolapse are the most common initial treatment. The ring pessary is usually changed every 3-6 months in our center. Pessary change can cause pain, which is usually more severe at removal than at re-insertion. There is some evidence that application of a local anaesthetic cream into the vagina can reduce the pain at removal. In our center, local anaesthetic cream is not used during pessary change. This study aims to evaluate a local anaesthetic cream compared to a placebo cream applied intravaginally before ring pessary change on pain during the change.

Who can participate?
Women attending the Gynaecology Clinic at the University Malaya Medical Centre (UMMC) for ring pessary follow-up and intend to continue using the ring pessary

What does the study involve?
Participants are randomly allocated to application of a local anaesthetic cream (lidocaine 2.5%, prilocaine 2.5%) as an active intervention OR application of a placebo cream as a control.
A 10 ml syringe will be used to introduce half of the content (2.5 ml of cream) into the centre of the ring pessary, and the other 2.5 ml in the lower vagina. The deposited cream will then be spread digitally over the deposited areas of the vagina.
After cream application, a timer is set for 5 minutes, following which the ring pessary is removed by the provider in the manner specified below. Speculum assessment of the vagina will be performed. If the re-insertion is still clinically appropriate it will be performed in the specific manner.
Participants will be asked if they feel tingling, stinging, burning, or itching 2 minutes after cream application and to rate pain right after pessary removal, right after the speculum examination and right after the new pessary is inserted. After the pessary change is complete, participants will be asked to rate their satisfaction with the pessary change process and whether they would recommend the local application of the allocated cream for ring pessary change to a friend. Before discharge from clinic, they will again be asked if experienced tingling, stinging, burning, or itching in the area of cream application.

What are the possible benefits and risks of participating?
The main benefit is that the patient will feel less pain at the pessary change with the effective cream. The main risk is that the patient may have reactions to the local study cream. No major benefit or harm is expected from the study interventions.

Where is the study run from?
Gynaecology Clinic at University Malaya Medical Centre (UMMC), Kuala Lumpur (Malaysia)

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

Who is funding the study?
Department of Obstetrics and Gynaecology, University Malaya Medical Centre (UMMC) (Malaysia)

Who is the main contact?
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Study website
https://www.ummc.edu.my/#

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Type(s)
Public, Scientific, Principal Investigator

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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
Local anaesthetic cream at ring pessary change: a double-blind randomised controlled trial

Acronym
LocAC

Study objectives
Use of local anaesthetic cream compared to placebo emollient cream before ring pessary removal will reduce pain during ring pessary change in the management of vaginal prolapse.

Ethics approval required
Ethics approval required

Ethics approval(s)

Approved 07/05/2025, Medical Research Ethics Committee of the University Malaya Medical Centre (Lembah Pantai, Kuala Lumpur, 59100, Malaysia; +60 (0)3 7949 3209; ummc-mrec@ummc.edu.my), ref: 20241022-14336

Study design
Double-blind randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Pelvic organ prolapse managed by ring pessary

Interventions
Patients attending to Gynaecology Clinic University Malaya Medical Centre (UMMC) for ring pessary change will be screened for study eligibility. The eligibility assessment form (EAF) will be used for screening.

A Patient Information Sheet (PIS) will be provided and questions invited from potential participants and responded to by the recruiting provider. Written informed consent will be obtained from all participants. Participants' characteristics and data will be transcribed onto the Case Report Form (CRF).

The randomisation sequence is generated using an online randomizer in random blocks of 4 or 8, with the intervention allocated in a 1:1 ratio. A co-investigator not involved in recruitment generated the sequence. Allocation of intervention will be revealed by the opening of the lowest-numbered remaining sealed envelopes to the latest recruit.

Participants will then be randomised to:
1. Application of local anaesthetic cream (lidocaine 2.5%, prilocaine 2.5%) as active intervention OR
2. Application of placebo cream as control

Cream application:
The 10 ml syringe will be used to introduce half of the content (2.5 ml of cream) into the centre of the ring pessary, and the other 2.5 ml in the lower vagina. The deposited creams will then be spread digitally over the deposited areas of the vagina.

After cream application, a timer is set for 5 minutes, following which the ring pessary is removed by the provider in the manner specified below. Speculum assessment of the vagina will be performed. If the re-insertion is still clinically appropriate, it will be performed in the manner specified below.

Study intervention materials:
1. Name of Product: EMLA® (Eutectic Mixture of Local Anesthetics) Cream
Active Ingredients: Lidocaine 2.5% and Prilocaine 2.5%
Formulation: Topical cream
Manufacturer: Aspen Pharmacare or AstraZeneca
Tube volume: 5 g
2. A placebo cream identical in appearance and texture to EMLA will be used in the control group to ensure blinding

Technique of removal and insertion of ring pessary:
Ring pessary removal technique:
The care provider will use the non-dominant hand to separate the labia, exposing the vaginal opening. With the dominant hand, the index finger will be hooked around the inner rim of the leading edge of the pessary, slightly tilting and rotating the pessary to disengage it from behind the pubic bone. The pessary will then be gently pulled downward and outward, following the natural curve of the vaginal canal toward the introitus, allowing it to fold naturally as it eases out of the vagina.

Speculum examination will be perform after pessary removal to check for vaginal erosions or abrasion to help decide on if re-insertion is warranted or to treat any vaginal lesion. This is a standard care procedure at ring pessary change.

Ring pessary insertion technique:
The care provider will hold the ring pessary horizontally with the dominant hand, placing the thumb and index finger at the 3 and 9 o'clock positions, compressing the ring into an oval shape to reduce its width. Using the non-dominant hand, the labia will be gently separated to expose the vaginal opening. The folded pessary will be inserted with the long axis parallel to the vaginal canal, angled slightly posteriorly toward the sacrum to follow the natural axis of the vagina. It will be advanced fully into the vaginal canal, past the pubic bone to rest in the posterior fornix. Once more than half of the compressed ring has been inserted, it will be gradually released to allow the pessary to open inside the vagina. The pessary will usually end up in the correct position without the need for much further adjustment. It may be guided upwards with the index finger to place the anterior edge behind the symphysis pubis, ensuring a secure fit.

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 immediate de novo or worsening of incontinence before she leaves the clinic.

Blinding:
The syringe will be labelled with a number identical to the randomisation number on the opaque envelope. The envelope will be marked with a use-by date, which will be within 14 days of the manufacture of the syringe containing the study creams. Unused envelopes beyond the use-by date will be discarded but the randomisation number will be reused.

The manufacture of the syringe will be conducted in a clean environment. The EMLA/control cream (5 ml) will be transferred from the tube into a 10 ml syringe by an investigator who will not be involved in recruitment, patient management or data collection. The syringe will be

labelled with the randomisation number according to the sequence generated for the allocated study cream. The number labelled syringe will be placed in an opaque envelope with the same number label externally visible. A use-by date will also be written on the randomisation envelope.

Expired envelopes will be discarded. The randomisation number and the allocated study cream for that number will be reused. The repackaging of the expired numbered envelopes will be performed by an investigator who will not be involved in recruitment, treatment or data collection.

Outcome Data Collection:
Two minutes after cream application, participants will be asked about tingling, stinging, burning and itching at the area of application; yes or no responses to each question.

Participants will be asked to rate their pain scores on an 11-point 0-10 Numerical Rating Scale (NRS), 0 as no pain to 10 as the worst pain imaginable:
1. Immediately after pessary removal
2. Immediately after completion of the speculum assessment
3. Immediately after pessary re-insertion

After successful ring pessary re-insertion, participant satisfaction with the ring pessary change process will be assessed using an 11-point 0-10 numerical rating scale (NRS) [higher score, greater satisfaction] and participants will be asked on the statement "I recommend the local application of my allocated cream for ring pessary change to a friend" using a 5-point Likert scale [Response options (choose one): Strongly agree, Agree, Neutral, Disagree or Highly disagree]

Before discharge from the clinic, participants will be asked about tingling, stinging, burning and itching at the area of application, yes or no response to each question.

Intervention Type
Other

Primary outcome measure
1. Pessary removal pain score using an 11-point 0-10 numerical rating scale (NRS) [0: No pain, 10: Worst pain imaginable] immediately after removal of ring pessary
2. Patient satisfaction with the ring pessary change assessed using an 11-point 0-10 numerical rating scale (NRS) [0: fully dissatisfied, 10: fully satisfied] after successful ring pessary re-insertion

Secondary outcome measures
1. Sensation felt in the area of cream application (i.e., vagina) assessed 2 minutes after application of allocated study cream:
a. Tingling: Yes/No
b. Stinging: Yes/No
c. Burning: Yes/No
d. Itching: Yes/No
2. Speculum vaginal examination pain score assessed using an 11-point 0-10 numerical rating scale (NRS) [higher score, greater pain] immediately after speculum examination
3. Pessary reinsertion pain score assessed using an 11-point 0-10 numerical rating scale (NRS) [higher score, greater pain] immediately after ring pessary re-insertion
4. Recommend the local application of allocated cream for pessary change to a friend, assessed

using a 5-point Likert scale [Strongly Agree, Agree, Neutral, Disagree, Highly Disagree response options] before clinic discharge
5. Sensation felt in the area of cream application (i.e., vagina) assessed before clinic discharge:
a. Tingling: Yes/No
b. Stinging: Yes/No
c. Burning: Yes/No
d. Itching: Yes/No

Overall study start date
01/04/2024

Completion date
30/08/2026

Eligibility

Key inclusion criteria
1. Attending clinic for ring pessary follow-up
2. PVC ring pessary in situ
3. Intends to continue using the ring pessary

Participant type(s)
Patient, Health professional

Age group
Mixed

Lower age limit
45 Years

Upper age limit
90 Years

Sex
Female

Target number of participants
114

Key exclusion criteria
1. Postmenopausal bleeding in the last 6 months (if not investigated)
2. Abnormal cervical cytology/histology (if not investigated)
3. Previous participation in the trial
4. Allergy history to lidocaine or prilocaine
5. Has underlying medical condition not suitable for local lidocaine or prilocaine application such as porphyria, G6PD deficiency and methemoglobinemia

Date of first enrolment
15/07/2025

Date of final enrolment
30/06/2026

Locations

Countries of recruitment
Malaysia

Study participating centre
Gynaecology Clinic, University Malaya Medical Centre (UMMC)
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Sponsor information

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Sponsor type
Hospital/treatment centre

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ROR
https://ror.org/00vkrxq08

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 peer-reviewed journal

Intention to publish date
01/07/2027

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date