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Using width or length assessed by digital examination for selecting the first ring size at ring pessary fitting for the management of vaginal prolapse

Submission date
11/11/2024

Recruitment status
No longer recruiting

Registration date
13/11/2024

Overall study status
Completed

Last Edited
17/06/2025

Condition category
Musculoskeletal Diseases

[X] 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
Pelvic organ prolapse (POP) is when one or more pelvic organ sag or bulge into the vagina or beyond resulting in the sensation of something coming down the vagina or problems with emptying the bladder and incontinence of urine, problems with passing motion and sexual dysfunction which can compromise quality of life. About 40% of women will experience POP in their lifetime and the incidence is highest in the 65 to 75 age group. Globally, the ring pessary is widely used as the first-line treatment for POP. Pessaries have to be sized and fitted for the individual patient. Pain is often felt when inserting and especially removing the ring pessary. Starting the fitting with a ring pessary of the correct diameter or as close as possible to the correct diameter will help to minimize the number of attempts needed in turn can reduce the pain related to fitting which will plausibly enhance patient satisfaction with the entire pessary fitting process. This study is conducted to evaluate if using vaginal length or maximum vaginal width obtained after standard digital vaginal examination is the more effective choice for selecting the first ring pessary diameter try in the ring pessary fitting process. The number of attempts before achieving a fit and women's satisfaction will be evaluated to show the effectiveness of one approach against the other. Neither the doctor performing the fitting nor the participant will know nor can choose to select vaginal length or width as the starting pessary diameter for the fitting. The assignment will be computer-generated.

Who can participate?
Female patients who have never been treated with a pessary or undergone repair surgery and where the shared decision has been made with their doctor to have their POP treated with a ring pessary

What does the study involve?
Recruitment will take place in a gynaecology clinic of a university hospital. Patients are provided with trial information and verbally engaged about the trial provided. informed written consent will be obtained from all who agree to participate. The severity of POP will be staged and digital

vaginal examination for determining length and width will be performed by a provider who will not be involved with pessary insertion or data collection. Both vaginal length and width will be obtained and recorded for each participant. Participants will be randomly assigned to apply with the vaginal width or length for the selection of the size of the first ring pessary for the fitting. A provider blinded to the starting ring pessary size selection process will insert the ring pessary and if necessary remove it using standard techniques. The process of fitting a ring pessary of the appropriate size will be carried out as usual, applying the principles of checking for pain and discomfort, ensuring pessary retention even with coughing, straining and movement, ability to pass urine and any new urinary incontinence or worsening of prior incontinence.

If the initial fitting is deemed unsuccessful, subsequent attempts can be made using a different ring pessary size as solely decided by the care provider according to best clinical judgement. The fitting is deemed to be successful when a participant is discharged with a ring pessary in place without issue. Participants provide a 0-10 satisfaction score of the fitting after a successful fitting before leaving the clinic, a 0-10 insertion pain score at first insertion and a 0-10 score of their experience on the use of the ring pessary at first follow-up 4-6 weeks after the fitting.

What are the possible benefits and risks of participating?
Both these widely applied pessary sizing methods can perform equally well or one method may perform better than the other on the outcomes studied. This study is to guide a common practical procedure. All study interactions are within routine clinic visits. The time patients spend specific to specific to the needs of the research is not expected to exceed 30 minutes. The ring pessary fitted will be provided free of charge. Significant complications caused directly by the study interventions are not anticipated. There may or may not be any immediate benefit to the participant.

Where is the study run from?
Department of Obstetrics and Gynaecology, University Malaya Medical Centre

When is the study starting and how long is it expected to run for?
March 2024 to December 2025

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

Who is the main contact?
Dr Noor Shafiqa Mohd Farid, shans_ones90@yahoo.com

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Principal investigator

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Additional identifiers

Study information

Scientific Title
Vaginal length vs width from digital assessment as the ring pessary diameter for initial pessary fitting in pelvic organ prolapse

Acronym
Pelvic organ prolapse (POP)

Study objectives
Evaluating using vaginal width or length as the starting ring pessary size on the number of attempts needed before achieving a fit and patients' satisfaction with the process of fitting

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 24/07/2024, Medical Research Ethics Committee (MREC), University Malaya Medical Centre (UMMC) (Jalan Profesor Diraja Ungku Aziz, Seksyen 13, Petaling Jaya, Kuala Lumpur, 50603, Malaysia; +603 7949 3209 / 2251 / 8473 / 4656; ummc-mrec@ummc.edu.my), ref: 2024612-13825

Primary study design
Interventional

Study design
Randomized controlled parallel-group study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Pelvic organ prolapse (POP)

Interventions

Recruitment will take place in the gynaecology clinic, at UMMC. Patients who are naïve to pessary management for POP will be assessed for eligibility, information and verbal engagement regarding the trial provided and informed written consent will be obtained from all participants. The Pelvic Organ Prolapse Quantification (POP-Q) System assessment tool and a 0-10 numerical rating scale (NRS) will be used to assess POP symptoms severity.
Digital vaginal examination for determining length and width will be performed by the provider who is not involved with pessary insertion or data collection. Vaginal length and width will be obtained and recorded for each participant. Participants will be randomized into either of two trial arms using either the vaginal width or length previously determined as the description above for the selection of the size of the first ring pessary. The assignment will be computer-generated. A provider blinded to the ring pessary size selection process will insert the ring pessary and if necessary remove it using standard techniques. The process of fitting a ring pessary of the appropriate size will be carried out as usual, applying the principles of checking for pain or discomfort, ensuring pessary retention even with movement, coughing, straining, ability to pass urine and any new urinary incontinence or worsening or prior incontinence. If the initial fitting is unsuccessful, subsequent attempts can be made using a different ring pessary size solely decided by the care provider according to best clinical judgement. The fitting is deemed to be successful when a participant is discharged with a ring pessary in place with no issue without issue. At 4 to 6 weeks follow up, the fit and patient satisfaction with the pessary use will be reassessed. In the event the participant does not attend follow-up, the participant will be contacted by telephone to get the updated information.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Number of insertions to final fit measured using data collected during fitting - If the fitting is unsuccessful, arbitrarily assigned as six insertions (at clinic discharge)
2. Participant satisfaction after successful fitting measured using the 11 points 0 - 10 numerical rating scale (NRS) - If the fitting is unsuccessful, arbitrarily assign arbitrary a score of 0 (at clinic discharge)

Key secondary outcome(s)
The following secondary outcome measures will be assessed at the clinic:
1. Care provider ease for the initial digital assessments of vaginal length and width using 11 points (using 0-10 NRS)
2. Pain score at first insertion (0 -10 NRS)
3. Difference in ring pessary diameter from initial to final fitted diameter (at clinic discharge after initial successful fitting)
4. Number of different pessary sizes used at fitting (at clinic discharge)

The following secondary outcome measures will be assessed at the 4-6 weeks follow-up:
5. Successful fitting, defined as the same ring pessary still in place without the need for interim reinsertion AND the same ring pessary replaced successfully if removal is clinically needed
6. Participant satisfaction with the ring pessary

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. Shared decision for a PVC ring pessary to treat POP
2. First time vaginal ring pessary insertion

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
30 Years

Upper age limit
100 Years

Sex
Female

Key exclusion criteria
1. Existing vaginal or vulvar laceration or ulcer
2. Vaginal infection
3. Previous vaginal repair (excluding childbirth related repair)
4. Postmenopausal bleeding in the last 6 months (if not investigated)
5. Abnormal cervical cytology / histology (if not investigated)

Date of first enrolment
02/12/2024

Date of final enrolment
30/11/2025

Locations

Countries of recruitment
Malaysia

Study participating centre
University Malaya Medical Centre, Kuala Lumpur
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Sponsor information

Organisation
University Malaya Medical Centre

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, 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
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Noor Shafiqa Mohd Farid, shans_ones90@yahoo.com. Available 12 months after publication for review board-approved individual patient data meta-analysis.

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	01/06/2024	13/11/2024	No	Yes

Protocol file	version 1.1	01/06/2024	13/11/2024	No		No