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# Distraction using sound and performance of a simple mental task compared to local anesthetic jelly application during intrauterine device insertion to reduce pain

**Submission date**
18/06/2026

**Recruitment status**
Recruiting

**Registration date**
30/06/2026

**Overall study status**
Ongoing

**Last Edited**
16/07/2026

**Condition category**
Urological and Genital Diseases

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

## Plain English summary of protocol

Background and study aims
An intrauterine device, or IUD, is a small device placed inside the womb to prevent pregnancy or to release hormones for medical reasons. It is inserted through the vagina and usually causes mild to moderate pain. In many places, including Malaysia, this procedure is often done without pain relief.
This study aims to compare two simple ways to reduce pain during IUD insertion. One uses a local anaesthetic jelly placed on the neck of the womb. The other uses a sound recording of rain with numbers, which encourages the person to focus and use their memory as a distraction. The study will find out if the sound and memory task can reduce pain as well as the anaesthetic jelly.

Who can participate?
Adults aged 18 years or older who are scheduled for an IUD insertion, are not pregnant, and have not had unprotected sex since their last normal period can take part.

What does the study involve?
Participants will be placed into one of two groups by chance. One group will listen to a recording of rain sounds with numbers spoken every 5 seconds. They will be asked to focus on the sounds and remember the largest number they hear. The recording will start 3 minutes before the procedure and continue until it ends.
The other group will receive a local anaesthetic jelly applied to the neck of the womb 3 minutes before the procedure.
All participants will have the IUD inserted using standard medical practice.
After the procedure, participants will rate the worst pain they felt and the average pain during the procedure on a scale from 0 to 10. About 15 minutes later, they will rate their satisfaction, report their current pain, and answer simple yes or no questions about symptoms such as dizziness, headache, nausea, or irritation. Participation ends when they leave the clinic.

What are the possible benefits and risks of participating?
Both methods may help reduce pain and improve comfort during IUD insertion. The study may also help improve care for women in the future.
The sound recording and memory task are expected to be safe, but may cause temporary dizziness or headache for some people. The anaesthetic jelly is also generally safe, though mild irritation or discharge may occur, and rare allergic reactions are possible. Some people may not need any pain relief for this procedure.

Where is the study run from?
University Malaya Medical Centre in Malaysia.

When is the study starting and how long is it expected to run for?
August 2026 to August 2027.

Who is funding the study?
Department of Obstetrics and Gynaecology, Faculty of Medicine, University Malaya.

Who is the main contact?
Dr Punitha Subramaniam, s.punitha@ummc.edu.my

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# Additional identifiers

# Study information

### Scientific Title
Sound combined with mental task versus cervical application of lignocaine jelly for pain relief during intrauterine device insertion: a randomized controlled trial

### Study objectives
Listening to a recording of rain sound embedded with a number series while trying to remember the largest number mentioned as a mental task would be non-inferior compared to the application of lignocaine jelly to the cervix on pain relief during insertion of an IUD

### Ethics approval required
Ethics approval required

### Ethics approval(s)
Approved 13/06/2026, Jawatankuasa Etika Penyelidikan Perubatan Pusat Perubatan Universiti Malaya (Jawatankuasa Etika Penyelidikan Perubatan Pusat Perubatan Universiti Malaya Lembah Pantai, Kuala Lumpur, 59100, Malaysia; +60 3-7949 3209 / 2251; ummc-mrec@ummc.edu.my), ref: 20251226-16070

### Primary study design
Interventional

### Allocation
Randomized controlled trial

### Masking
Open (masking not used)

### Control
Active

### Assignment
Parallel

### Purpose
Analgesia during intrauterine device insertion

### Study type(s)

### Health condition(s) or problem(s) studied
Intrauterine device placement as medically indicated

## Interventions

For participants assigned to intervention of sound combined with mental task, the process required will be explained to them after the opening of the opaque envelope allocated to them. It will be explained that after the cervix is exposed with the Cusco speculum, a recording of rain sounds will be played and every 5 seconds a number will be mentioned. The participants will be instructed to listen and focus on the rain sounds and to retain in their memory the largest number mentioned in the series until the end of the procedure. Three minutes into the recording to allow the recording's effect to take place, the usual standard IUD insertion process will then start.

For participants assigned to intervention of Lignocaine 2% jelly applied to the cervix, the process will be explained to them after the opening of the opaque envelope allocated to them. It will be explained that after the cervix is exposed with the Cusco speculum, Lignocaine 2% jelly will be applied under direct vision to the surface of the external opening of the cervical canal. Three minutes after the start of application of lignocaine jelly to allow jelly's effect to take place, the usual standard IUD insertion process will then start.

All participants will be prepared for IUD insertion according to local protocol. The bivalve vaginal speculum (Cusco) will be used to expose the cervix.

Standard protocol for IUD insertion(1, 2):
1. After obtaining inform consent, patient will be positioned in lithotomy position.
2. A bimanual examination performed to determine whether the uterus is anteverted or retroverted.
3. Cusco speculum inserted vaginally to identify the cervix. Cervix and vaginal fornices are cleaned.
4. Depending on cervical findings through the Cusco speculum, the cervical lip maybe grasped using tenaculum and gentle traction applied to straighten the cervical canal and uterine cavity. However, if cervical and bimanual examination findings are favourable, tenaculum use may not be necessary.
5. Using a sterile uterine sound, the depth of the uterine cavity determined, typically between 6 and 9 cm. Once uterine depth is determined, set the IUD inserter as per individual manufacturer' s instruction, then gently pass the inserter through the cervix to reach the fundus, release the IUD inside the uterine cavity, and remove the
inserter.
6. Once the IUD is inserted, the strings are cut to 3 to 4 cm with sharp scissors.
7. Once IUD inserted, the tenaculum removed if used, ensuring no bleeding from the tenaculum site, and finally, the speculum is removed.
8. After the insertion, the woman rests. She remains on the examination table until she feels ready to get dressed.

A. Sound combined with mental task
The sound recording will be delivered using an iPhone through the use of headphones. The recording will be started and the time recorded as the start time of the intervention. Three minutes after, the standard (usual) process of IUD insertion in accordance with the manufacturer' s instruction will then follow. The recording will be stopped on completion or abandonment of IUD insertion (i.e., removal of Cusco speculum). The time of completion or abandonment will be recorded.

The rain sound background will be an original recording. The 2 digit numbers spoken every 5 seconds will also be generated as an original sequence specific to the study. This sound track will run for 10 minutes and auto -repeated until the end of the procedure. Volume will be set at 40

decibels for background rain sounds and 60 decibels for the numbers as sound levels considered safe as per the American Academy of Audiology's Noise Chart.

B. Lignocaine 2% jelly (10g)
The Lignocaine 2% jelly will be applied on cervix under direct visualization using syringe 5ml (10g) through a 10ml syringe. 3 minutes after jelly application onto the surface of cervix, the standard process of IUD insertion in accordance with the manufacturer's instruction will then follow. The time of completion or abandonment (i.e., removal of Cusco speculum) will be recorded.

If insertion could not proceed because of pain, the provider may offer cross -over opposite intervention if appropriate before abandonment. Any cross -over will be recorded.

### Intervention Type
Mixed

### Primary outcome(s)
1. Maximum (peak) pain score experienced during IUD insertion measured using Numerical Rating Scale (0 no pain to 10 worst pain imaginable) at within 5 minutes of the end of the procedure

2. Average pain during IUD insertion measured using Numerical Rating Scale (0 no pain to 10 worst pain imaginable) at within 5 minutes after completion of the procedure

3. Patient satisfaction with allocated intervention measured using Numerical Rating Scale (0 completely dissatisfied to 10 completely satisfied) at 15 minutes after completion of the procedure

4. Current lower abdomen-perineum pain measured using Numerical Rating Scale (0 no pain to 10 worst pain imaginable) at 15 minutes after completion of the procedure

5. IUD insertion success measured using clinical assessment and procedure record (successful placement of IUD versus unsuccessful or abandoned insertion) at completion of the procedure

6. IUD insertion time measured using procedure timing recorded using clinical procedure records or stopwatch (time from start of allocated intervention to removal of Cusco speculum) at during the procedure, recorded at completion or abandonment

7. Post-procedure symptoms including dizziness, headache, vaginal irritation, nausea, palpitations, shortness of breath, and tremor measured using symptom questionnaire with Numerical Rating Scale and yes or no responses at 15 minutes after completion of the procedure and at end of data collection

### Key secondary outcome(s)

### Completion date
01/08/2027

## Eligibility

### Key inclusion criteria

1. Scheduled for IUD insertion as medically indicated
2. Premenopausal adults (18 years old and above)
3. Not pregnant (no unprotected sexual intercourse since last normal menstrual period)

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 Years

### Upper age limit
60 Years

### Sex
Female

### Total final enrolment
0

### Key exclusion criteria
1. Suspicion of pregnancy
2. Current diagnosis of vaginal or pelvic infection
3. Neuropathic disabled patients from below waist
4. Known structural abnormality of the uterus
5. Lignocaine allergy
6. Usage of analgesics within 24 hours of the procedure
7. History of ectopic pregnancy
8. Unexplained abnormal vaginal bleeding
9. Contraindication to intrauterine device or system
10. Lack of capacity to provide consent for any reason (e.g., language difficulties, etc)

### Date of first enrolment
01/08/2026

### Date of final enrolment
01/08/2027

## Locations

### Countries of recruitment
Malaysia

## 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**
Data sharing statement to be made available at a later date

**Study outputs**

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | version 1 | 01/03/2026 | 18/06/2026 | No | Yes |