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# Concurrent Foley catheter and prostaglandin vaginal insert compared to Foley catheter only for induction of labour in first time mothers with obesity

**Submission date**
12/09/2025

**Recruitment status**
No longer recruiting

**Registration date**
25/09/2025

**Overall study status**
Completed

**Last Edited**
15/09/2025

**Condition category**
Pregnancy and Childbirth

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

## Plain English summary of protocol

Background and study aims
Induction of labour (IOL) is a very common procedure: in 2018, in the USA, the IOL rate was 37.8% in first-time births. In many countries by 2014, more than half of pregnant women were overweight, and nearly a third were obese. IOL usually starts with a cervical ripening process, as often the cervix (neck of the womb) is initially closed and firm (unyielding). The Foley catheter balloon (a mechanical method) and prostaglandins (a medicine, e.g. dinoprostone) placed vaginally are the most common methods used for cervical ripening in contemporary practice. They are usually applied on their own for that purpose. At IOL, first-time mothers, unripe cervixes and obesity are major risk factors for failure to achieve a normal vaginal delivery. The combination of these risk factors within an individual carries a high risk that the IOL will fail, resulting in an unplanned caesarean birth. The Foley catheter balloon (a mechanical method) and dinoprostone (a prostaglandin) drive cervical ripening through different pathways. Combining them may thus be a complementary approach that may safely improve the cervical ripening and labour process, which may reduce the need for Caesarean birth during IOL. This study plans to compare the Foley catheter balloon and controlled-release dinoprostone vaginal insert applied concurrently to the Foley catheter balloon alone (the current standard method for cervical ripening) for a planned 24-hour placement to start IOL in high-risk first-time mothers with obesity and unripe cervixes to evaluate their respective impact on Caesarean births.

Who can participate?
Obese patients at term with a single baby requiring cervical ripening in their IOL

What does the study involve?
The participants will receive standard care through their IOL, labour, delivery and to their hospital discharge, except initiation of cervical ripening in their IOL. Participants will have a Foley catheter inserted and a dinoprostone insert placement immediately following their Foley catheter insertion or have a Foley catheter inserted on a random basis (i.e., neither the patient nor their care provider can choose; the allocation is through a computerised process). These

devices are passively left in position for up to 24 hours to effect ripening or labour if there are no interim events requiring other care. Monitoring, care and decision making during cervical ripening, labour and delivery will be according to standard institutional protocol and at the sole discretion of participants' care providers applying their normal practice in their patients' best interest. There is no additional active involvement expected on the part of participants beyond providing a satisfaction score after delivery.

What are the possible benefits and risks of participating?
Plausible benefit: A concurrent Foley catheter and dinoprostone insert may reduce caesarean delivery by enhancing cervical ripening and improving labour compared with a Foley catheter balloon alone at initiation of IOL.
Plausible risks: The addition of vaginal dinoprostone may expedite and strengthen womb contractions. This may cause abnormalities in the baby's heartbeat and result in caesarean delivery compared to a Foley catheter alone, even if there are measures available to reduce excessive womb contractions.

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

When is the study starting and how long is it expected to run for?
May 2025 to 31 October 2026

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

Who is the main contact?
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# Additional identifiers

**Clinical Trials Information System (CTIS)**
Nil known

**Protocol serial number**
RSCH ID-25-03481-OIU

# Study information

**Scientific Title**

Concurrent Foley catheter and controlled-release dinoprostone vaginal insert versus Foley catheter for labour induction in obese nulliparas: a randomized controlled trial

## Acronym
ObeNull Study

## Study objectives
Concurrent Foley catheter and controlled-release dinoprostone vaginal insert compared to Foleys catheter alone for a planned 24 hours placement for the induction of labour (IOL) of obese nulliparas will reduce caesarean delivery rate.

## Ethics approval required
Ethics approval required

## Ethics approval(s)
Approved 21/05/2025, Medical Research Ethics Committee (University Malaya Medical Centre (University Malaya Medical Centre (UMMC) Lembah Pantai, Kuala Lumpur, 59100, Malaysia; +603-79493209/2251; ummc-mrec@ummc.edu.my), ref: 2025127-14655

## Primary study design
Interventional

## Study design
Single-centre parallel-group convenience-sampled randomized controlled trial

## Study type(s)
Treatment

## Health condition(s) or problem(s) studied
Obese nulliparas
Induction of labour

## Interventions
All participants will have a Foley catheter inserted, but participants randomised to the combined regime will have dinoprostone insertion immediately following their Foley catheter insertion. The randomisation sequence will be generated in random blocks of 4 or 8 using an online randomiser (https://www.sealedenvelope.com/simple-randomiser/v1/lists) by an investigator not involved in the recruiting or care process. Numbered sealed opaque envelopes will be prepared to conceal the allocated intervention. The lowest numbered envelope remaining will be opened to reveal the allocated intervention for the newest recruit.

Cervical status will be obtained before Foley insertion. At the inserter's discretion, an 18F Foley catheter will be inserted transcervically digitally or by speculum. Once the tip of the catheter has passed the internal os by 4 to 5 cm, the balloon will be inflated with 30 ml of water and retracted so the balloon rests on the internal cervical os. The external end of the Foley will be occluded and then taped without tension to the participant's thigh.
In the combined arm, following Foley catheter insertion, the controlled-release dinoprostone insert 10 mg will be immediately placed by holding the vaginal delivery system between the index and middle finger, inserting it in the vagina and placing it crosswise high up in the rear fornix of the vagina. If required, a small amount of water-soluble lubricant can be used. The external tape is cut to a sufficient length to run outside the introitus to permit retrieval if

needed.
Immediately after the insertion of trial devices, cardiotocography will be started in both arms and continued until such time as it is ascertained to be fully reassuring. Both trial devices are planned to be left in place passively for 24 hours.
Trial devices can be removed by providers at their discretion for clinical reasons at any time. Following removal, standard IOL care will be applied. The vaginal insert can be separately retrieved with the Foley left in situ if deemed clinically appropriate, e.g. for excessive uterine contractions.
After the trial device (Foley and controlled release dinoprostone vaginal insert or Foley only, as randomised) removal, onward labor management will be at the discretion of the attending obstetrician, in keeping with the pragmatic study design.

## Intervention Type
Mixed

## Primary outcome(s)
Caesarean delivery rate measured using data collected in patient medical records at one timepoint

## Key secondary outcome(s)
The secondary outcome measures are measured using data collected in patient medical records at one timepoint, unless stated:
Maternal secondary outcomes:
1. Cervical ripeness measured using the Bishop score at removal/retrieval of trial devices
2. Maternal satisfaction with their induction method measured using the 0-10 Numerical Rating Scale (higher score, greater satisfaction)
3. Recommendation of the allocated method of IOL to a friend measured using a 5-grade Likert scale response (Strongly Agree-Agree-Neutral-Disagree-Strongly Disagree)
4. Additional cervical ripening method if needed
5. Intrapartum oxytocin use (excluding use for PPH prophylaxis)
6. Induction to delivery interval
7. Mode of delivery
7.1. Spontaneous
7.2. Vacuum
7.3. Forceps
7.4. Caesarean section
8. Indication for caesarean section
9. Indication for instrumental vaginal delivery
10. Blood loss during delivery
11. Perineal condition after birth (Intact/First/Second/Third/Fourth/Episiotomy)
12. Maternal infection (Temperature ≥38.0 0C)
13. Epidural in labour
14. Length of hospital stay
15. ICU admission
16. Cardiorespiratory arrest
17. Needing a hysterectomy

Neonatal outcomes:
1. Apgar score at 1 and 5 minutes
2. NICU admission
3. Cord pH

4. Neonatal sepsis
5. Birth weight
6. Birth trauma
7. Hypoxic ischaemic encephalopathy/need for therapeutic hypothermia

### Completion date
31/10/2026

## Eligibility

### Key inclusion criteria
1. Planned induction of labour (irrespective of indication)
2. BMI ≥30.0kg/m2
3. Nulliparous (no previous pregnancy ≥ 22 weeks)
4. Unfavourable cervix
5. Intact membrane
6. Term ≥37 weeks
7. Age 18-45 years old
8. Singleton pregnancy
9. Cephalic presentation
10. Normal fetal heart rate tracing on cardiotocograph before induction
11. Absence of significant contractions (≥ 2 in 10 minutes)

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 Years

### Upper age limit
45 Years

### Sex
Female

### Key exclusion criteria
1. Previous uterine scar
2. Known major fetal anomaly
3. Fetal weight clinically estimated to be less than 2 kg or more than 4 kg
4. Maternal infection
5. Contraindication for vaginal delivery
6. Latex allergy
7. Dinoprostone allergy

**Date of first enrolment**
01/10/2025

**Date of final enrolment**
30/09/2026

# Locations

**Countries of recruitment**
Malaysia

**Study participating centre**
**Universiti Malaya Medical Centre (UMMC), Kuala Lumpur**
Universiti Malaya, Pusat Perubatan Universiti Malaya (PPUM)
Lembah Pantai
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# 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 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

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | version 1.0 | 24/01/2025 | 15/09/2025 | No | Yes |