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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
Not yet recruiting

Registration date
25/09/2025

Overall study status
Ongoing

Last Edited
15/09/2025

Condition category
Pregnancy and Childbirth

[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
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?
1. Dr Khairun Nurlisa binti Kamal, knk121191@gmail.com
2. Professor Vallikannu Narayanan, nvalli@um.edu.my
3. Professor Tan Peng Chiong, tanpengchiong@yahoo.com
4. Dr. Wong Thai Ying, thai.wong@um.edu.my

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Dr Khairun Nurlisa Kamal

Contact details
University of Malaya Medical Centre, University of Malaya
Lembah Pantai
Malaysia
59100
+60174988313
knk121191@gmail.com

Type(s)
Public, Scientific, Principal Investigator

Contact name
Prof Peng Chiong Tan

Contact details
University of Malaya Medical Centre, University of Malaya
Lembah Pantai
Malaysia
59100
+603 79492049
pctan@um.edu.my

Type(s)
Public, Scientific, Principal Investigator

Contact name
Prof Vallikannu Narayanan

Contact details
University of Malaya Medical Centre, University of Malaya
Lembah Pantai
Malaysia
59100
+603- 7841 4000
nvalli@um.edu.my

Type(s)
Public, Scientific, Principal Investigator

Contact name
Dr Thai Ying Wong

Contact details
University of Malaya Medical Centre, University of Malaya
Lembah Pantai
Malaysia
59100
+6016-945 9213
thai.wong@um.edu.my

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers

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

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital, Medical and other records

Study type(s)
Treatment

Participant information sheet
See study outputs table

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 measure
Caesarean delivery rate measured using data collected in patient medical records at one timepoint

Secondary outcome measures
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

Overall study start date
21/05/2025

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

Age group
Adult

Lower age limit
18 Years

Upper age limit

45 Years

Sex
Female

Target number of participants
324

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
Malaysia
59100

Sponsor information

Organisation
University Malaya Medical Centre

Sponsor details
University of Malaya
Lembah Pantai
Malaysia
59100

+603-7949 4422
ummc@ummc.edu.my

Sponsor type
Hospital/treatment centre

Website
https://www.ummc.edu.my

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

Publication and dissemination plan
Planned publication in a peer-reviewed journal

Intention to publish date
31/08/2027

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

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