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Placing the Foley balloon catheter adjacent to the inner portion of the neck of the womb for 12 compared to 24 hours to induce labour in women who had one prior caesarean birth

Submission date
14/05/2024

Recruitment status
No longer recruiting

Registration date
25/05/2024

Overall study status
Completed

Last Edited
08/08/2025

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

Both caesarean section and induction of labour have become common. Current trends indicate their occurrence is continuing to increase. As a result, the need for labour induction in a subsequent pregnancy having had a prior caesarean is also more commonly encountered. Induction of labour after one previous cesarean (IOLAC) is a high-risk procedure as a failed induction resulting in unplanned Caesarean delivery is common and there is a small chance of the previous caesarean scar on the uterus breaking open. Hence, IOLAC is only acceptable in well-motivated and well-informed women who are delivering in a well-resourced hospital capable of a rapid caesarean when it is needed. Apart from the satisfaction arising from achieving a desired vaginal birth after caesarean instead of another caesarean delivery, complications are less frequent for the mother in future pregnancies. The Foley catheter balloon (inflated to 30-80 ml) is commonly used to help open (ripen) the closed cervix (neck of the womb) as the initial step in labour induction in our centre. Balloon ripening during labour induction results in fewer complications for the baby compared to using medicines like prostaglandins. The process of ripening with the Foley balloon is typically not painful as contractions are not generated. After the cervix has opened sufficiently (usually to 3 cm or more), the forewaters can then be broken and the oxytocin drip started to start contractions (labour pain) leading to labour and birth. The usual practice is to leave the Foley balloon in place for 12 to 24 hours after insertion before removing it to check if the cervix has opened enough to allow the forewaters to be broken. Preliminary data indicate that Foley balloon placement for 12 or 24 hours will produce broadly similar major outcomes. In many women, the balloon can pass through the sufficiently opened cervix several hours after insertion but is retained within the vagina without causing discomfort. This scenario of the balloon in the vagina, if not discovered earlier (by 12- versus 24-hour placement before reassessment) can delay the breaking of forewaters, starting the oxytocin drip to initiate contractions and plausibly of birth too. Mothers' satisfaction is widely recognised as an important outcome to take into consideration when conducting studies on interventions to improve care at induction of labour.

Who can participate?
Patients with one previous cesarean section scar planned for induction of labour for various indications and admitted to the antenatal or labour ward, University Malaya Medical Centre.

What does the study involve?
This study involves an assessment of mothers' satisfaction based on exposure to 12 or 24 hours of Foley catheter balloon placement for IOLAC and also of the role that maternal choice may play in decision-making in driving maternal satisfaction with labour induction and birth.
About half of those participating will be allocated to one of the two trial interventions (only after a Foley balloon has been successfully placed through the cervix to sit adjacent to the internal opening of the cervix to expedite cervical ripening in the process of inducing labour):
1. To passively allow the Foley balloon to remain in place for 12 hours (about one-quarter of all participants)
OR
2. To passively allow the Foley balloon to remain in place for 24 hours (about one-quarter of all participants)
before Foley balloon removal to check that the cervix has ripened.

About half of those participating who have a preference will choose (after a successful Foley balloon), by their own will
1. To passively allow the Foley balloon to remain in place for 12 hours (about one-quarter of all participants)
OR
2. To passively allow the Foley balloon to remain in place for 24 hours (about one-quarter of all participants)

What are the possible benefits and risks of participating?
Mothers' satisfaction may or may not be higher and time to birth may or may not be quicker with the Foley balloon placement durations under study.
Major complications or risks are not anticipated arising from the interventions. It is possible that following catheter dislodgement or after removal, the cervix may not be sufficiently opened for breaking of the forewaters and further ripening measures will need to be considered as part of standard care.

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?
December 2023 to June 2025

Who is funding the study?
Department of Obstetrics and Gynecology, Faculty of Medicine, University Malaya, Malaysia

Who is the main contact?
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Contact information

Type(s)

Public, Scientific, Principal investigator

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Study information

Scientific Title
12 vs 24 hours Foley balloon placement in the induction of labour after one previous cesarean: a pragmatic randomized controlled trial

Acronym
IOLAC

Study objectives
A planned 12 vs 24 hours placement of the Foley balloon for cervical ripening in Induction of Labour after One Previous Caesarean (IOLAC) and whether the planned 12 vs 24 hours placement is by choice or as randomly assigned, affects maternal satisfaction with their birth experience

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 08/04/2024, Medical Research Ethics Committee, University Malaya Medical Centre (Lembah Pantai, Kuala Lumpur, 59100, Malaysia; +60 03-79493209/2251; ummc-mrec@ummc.edu.my), ref: 20231228-13183

Primary study design
Interventional

Study design
Single-centre parallel-group randomized controlled trial

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Induction of labour after one previous caesarean section

Interventions
Patients are screened on their admission for their planned labour induction for eligibility to participate in the trial. They will be given written and verbal information about the trial. All participants who agree to take part will provide informed written consent.

About half of those participating who accept will be randomised to one of the two trial interventions (only after a Foley balloon has been successfully placed through the cervix to sit adjacent to the internal opening of the cervix to expedite cervical ripening in the process of inducing labour):
1. To passively allow the Foley balloon to remain in place for 12 hours (about one-quarter of all participants)
OR
2. To passively allow the Foley balloon to remain in place for 24 hours (about one-quarter of all participants)
before Foley balloon removal to check that the cervix has ripened.

About half of those participating who have a preference will choose (after a successful Foley balloon), by their own will
1. To passively allow the Foley balloon to remain in place for 12 hours (about one-quarter of all participants)
OR
2. To passively allow the Foley balloon to remain in place for 24 hours (about one-quarter of all participants)

Standard induction care is applied at all times. If the Foley balloon is expelled before scheduled removal, standard induction care will follow in response including amniotomy and commencing titrated oxytocin infusion in furtherance of achieving labour and birth.

Randomisation is by opening the lowest number, sealed and opaque envelope that is available for the newest recruit. The randomization sequence will be generated using an online randomiser in random blocks of 4 or 8 by an investigator who is not involved in recruitment.

Blinding is not feasible due to the nature of the intervention and the design of the study.

Before, during and after labour induction to hospital discharge, participants will receive the standard labour care including periodic monitoring of the mother and baby, indicated prophylactic measures and treatments, arrangements for hospital discharge and postnatal follow-up.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Maternal satisfaction with the birth experience will be assessed using the following measures before hospital discharge:
1. 12 vs 24 hours duration of Foley balloon placement using a 0-10 numerical rating scale (NRS)
2. Choice vs Randomized using a 0-10 NRS
3. 12-hour duration by choice vs 12-hour duration as randomized using a 0-10 NRS
4. 24-hour duration by choice vs 24-hour duration as randomized using a 0-10 NRS

Key secondary outcome(s)

Maternal Outcomes:
1. Maternal satisfaction with the Foley placement regimen will be assessed using the following measures before hospital discharge:
1.1. 12 vs 24 hours duration of Foley balloon placement using a 0-10 numerical rating scale (NRS)
1.2. Choice vs Randomized using a 0-10 NRS
1.3. 12-hour duration by choice vs 12-hour duration as randomized using a 0-10 NRS
1.4. 24-hour duration by choice vs 24-hour duration as randomized using a 0-10 NRS

2. Response to whether they will recommend their intervention of 12 hours or 24 hours for Foley catheter placement for IOL to a friend measured using a Likert scale (5-grade; strongly agree to strongly disagree) before hospital discharge

The following measures are assessed using data collected from medical records at the end of the study:
3. Change in bishop score after intervention
4. Use of additional method for cervical ripening
5. Time to delivery after Foley insertion
6. Time to delivery after Foley removal/ expulsion
7. Mode of delivery
8. Indication for cesarean section
9. Duration of oxytocin infusion
10. Blood loss during delivery
11. Third- or fourth-degree tear
12. Maternal infection (fever ≥ 380C)
13. Use of regional analgesia in labour (epidural)
14. Length of hospital stay
15. ICU admission
16. Needing hysterectomy

The following neonatal outcome measures are assessed using data collected from medical records, unless stated, at the end of the study:
1. Newborn health measured using Apgar scoring at 1 and 5 minutes
2. NICU admission
3. Cord artery pH
4. Neonatal sepsis
5. Birth weight
6. Birth trauma
7. Hypoxic ischaemic encephalopathy/need for therapeutic hypothermia

Completion date
02/06/2025

Eligibility

Key inclusion criteria
1. Scheduled labour induction
2. One previous lower segment caesarean
3. Singleton fetus (one baby)
4. Term: ≥ 37 weeks of pregnancy
5. 18 years and above
6. Cephalic presentation (head first)

7. Reassuring fetal heart rate tracing (baby in good condition)
8. Unripe cervix (Modified Bishop Score ≤ 6)
9. Absence of significant painful contraction (≥ 2 in 10 minutes)
10. Intact membranes
11. Successful Foley balloon insertion for IOL

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Female

Key exclusion criteria
1. Latex Allergy
2. Estimated fetal weight ≤ 2kg or ≥ 4kg before induction and confirmed by ultrasound
3. Known major fetal malformations
4. Contraindications for vaginal delivery

Date of first enrolment
15/06/2024

Date of final enrolment
31/03/2025

Locations

Countries of recruitment
Malaysia

Study participating centre
University Malaya Medical Centre
Lembah Pantai
Kuala Lumpur
Malaysia
59100

Sponsor information

Organisation
University Malaya Medical Centre

ROR
https://ror.org/00vkrxq08

Funder(s)

Funder type
Not defined

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 Aimi Dayana Binti Harun, aimidayana@ummc.edu.my

IPD sharing plan summary
Available on request