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Comparison of removal of Foley's catheter at 6 versus 12 hours post-induction of labor in women who have not given birth before

Submission date
22/12/2021

Recruitment status
No longer recruiting

Registration date
10/01/2022

Overall study status
Completed

Last Edited
05/02/2025

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
In developed countries, approximately 20–25% of pregnant women undergo labor induction, many of whom require cervical ripening. The goal of induction of labor (IOL) is to achieve vaginal delivery by stimulating uterine contractions before the spontaneous onset of labor. Generally, induction of labor has merit as a therapeutic option when the benefits of expeditious delivery outweigh the risks of continuing the pregnancy.

Time to delivery is an important consideration during IOL because of its association with increased risk of caesarean delivery, postpartum hemorrhage, and maternal and neonatal infections. Moreover, a lengthy IOL process can overburden busy delivery wards, can contribute to rising healthcare costs, and is associated with lower patient satisfaction scores.

A catheter is a long, flexible tube with an inflatable balloon at one end that can be expanded after insertion with air or sterile water. One method for inducing labor uses a catheter inserted into the cervix with the balloon then dilated within the womb (uterus), to help the cervix dilate so that the baby can pass through.

The aim of this study is to evaluate the effect of the placement of a low-cost catheter with a single balloon (known as a Foley catheter) for 6 vs 12 hours in women who have not given birth before, with unripe services, who are planned for IOL. A previous study using a different type of catheter (known as a double-balloon catheter), that has two balloons (which are dilated on either side of the cervix, in the uterus and vaginal canal respectively), suggested that earlier catheter removal is associated with a faster time to delivery.

Who can participate?
Women at 37 weeks gestation or more, scheduled for labour induction, who are aged 18 years or older and have not given birth before.

What does the study involve?
The Foley catheter is usually inserted manually into the lower womb, although a vaginal

speculum can be used if insertion is unsuccessful. The balloon near the tip of the catheter is then inflated with 80 ml of sterile water. After the balloon has been inflated and retained, the external tubing of the catheter will be taped to the inner thigh and the participant can move around freely and perform bodily functions without any impairment.
Once the catheter has been placed a CTG (cardiotocograph) scan will be done to monitor the fetal heartbeat and the uterine contractions. Then participants will be randomly assigned to one of the two treatment groups, with an equal chance of being assigned to either group (like tossing a coin). Group 1 will have the removal of foley's catheter 6 hours after the induction of labor. Group 2 will have the removal of foley's catheter 12 hours after the induction of labor.

What are the possible benefits and risks of participating?
This study will be used to provide knowledge on the time of placement of a Foley catheter to induce labour and how it affects the time from induction to delivery. The results of this study might change standard care for future patients.

The Foley catheter insertion may cause some pain or discomfort, occasionally may cause mild vaginal bleeding, and uncommonly may cause difficulty in passing urine. Major complications are not anticipated. Induction in women who have never given birth before usually takes a longer time than in those who have, and therefore despite balloon expulsion, in the absence of regular contractions, 90% of women induced with Foley catheter require breaking of waters and a hormone drip to initiate 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?
From October 2021 to August 2023

Who is funding the study?
University Malaya (Malaysia)

Who is the main contact?
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Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
6 hours vs 12 hours of Foley catheter placement for labor induction in nulliparas with unripe cervices: a randomized trial

Acronym
FOCAPIN

Study objectives
Removal at 6 compared to 12 hours of the Foley catheter in nulliparas will shorten induction to delivery time

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/10/2021, University of Malaya Medical Centre Medical Research Ethics Committee (Lembah Pantai, 59100 Kuala Lumpur, Malaysia; +60 (0)3 7949 8473; ummc-mrec@ummc.edu.my), ref: MREC ID: 2021107-10672

Study design
Randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)

Hospital

Study type(s)
Treatment

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Induction of labour

Interventions
This is a planned randomised control trial. All eligible women will be approached, provided with the Patient Information Sheet, verbally counseled, and their queries answered by the care provider for their informed consenting. Women agreeing to participate will be asked for their written consent.

All participants will undergo a standard assessment by their care provider before their induction of labor; including their personal characteristics, obstetric assessment, and fetal wellbeing (using a non-stress cardiotocogram) assessment.

Participants will be positioned in the dorsal position. Bishop score will be ascertained during the vaginal examination prior to Foley insertion. A Foley catheter size 16F is then introduced through the external os using either digital or speculum method (at the discretion of introducer). Once the tip of the catheter has passed the internal os by 4-5 cm, the balloon will be inflated with 80ml of water and retracted so the balloon rests on the internal cervical os. The other end of the Foley catheter will be taped without tension to the medial aspect of the women’s thigh.

Randomisation will be performed and intention to treat revealed only after successful Foley insertion. Randomisation is done by opening the lowest number, sealed and opaque envelope that is available, assigned in strict order. The randomisation sequence will be generated using a random number generator at Random.org in random blocks of 4 or 8 sequence, generated by an investigator who is not involved in recruitment. Blinding is not possible due to the nature of the intervention. Participants will be randomised into two trial arms: Foley removal at 6 h or 12 h following its insertion.

Standard care for Foley IOL in our centre is applied to both arms. They are allowed to ambulate. Analgesia is given upon request. Cardiotocogram is performed as indicated. Patients are transferred to the labor and delivery suite if the catheter is spontaneously expelled before the designated 6 or 12 h. The catheter is removed if a spontaneous rupture of the membrane occurs or there is a clinical need as decided at the discretion of the care provider.

Upon Foley removal (or if spontaneously expelled before removal), a second Bishop score is recorded, artificial rupture of membranes performed, and oxytocin infusion is initiated according to standard IOL protocol (10 international units of oxytocin in 500 mmls of Hartmann solution, started at 6 ml/h [2 mU/min] and doubled every 30 min until 3–5/10 min regular painful contractions is achieved at which rate infusion rate is maintained to delivery if no untoward reaction, maximum dose at 96 ml/h [32 mU/min]. If artificial rupture of membranes is not possible or safe (i.e. - fetal head at high station), oxytocin can be initiated prior to artificial rupture of membrane.

Failed ripening is diagnosed if Bishop score is ≤5 after removal of the catheter. The patient will then be assessed and counseled by the care provider as standard care in these circumstances for medical induction with prostaglandin, oxytocin, another Foley, or caesarean section

Intervention Type
Procedure/Surgery

Primary outcome measure
Time to delivery after induction measured from the time of induction and the time of delivery recorded in the Case Report Form at induction of labour and delivery

Secondary outcome measures
Maternal outcomes:
1. Estimate of the readiness of the cervix for labor measured using Bishop score calculated before insertion of the catheter and after removal of the catheter
2. Use of additional method for cervical ripening measured from the Case Report Form after removal of the catheter
3. Time to delivery after Foley removal measured from the time of catheter removal and the time of delivery recorded in the Case Report Form at removal of the catheter and delivery
4. Mode of delivery measured from the Case Report Form at delivery
5. Indication for caesarean section measured from the Case Report Form at delivery
6. Duration of oxytocin infusion measured from the Case Report Form after oxytocin infusion
7. Maternal satisfaction-based allocation to intervention until birth measured using 11-point Verbal Numerical Rating Score (VNRS) at the end of the study
8. Blood loss during delivery measured from the Case Report Form at delivery
9. Third -or fourth-degree tear measured from the Case Report Form at delivery
10. Maternal infection measured from data in the Case Report Form collected throughout the study
11. Use of regional analgesia in labour measured from the Case Report Form at delivery
12. Length of hospital stay measured from the time of admission and the time of discharge recorded in the Case Report Form between hospital admission and discharge
13. Need for ICU admission measured from data in the Case Report Form collected throughout the study

Neonatal outcomes:
1. Neonatal health measured using Apgar score at 1 and 5 min after delivery
2. Need for NICU admission measured from the Case Report Form collected throughout the study
3. Fetal metabolic condition measured using Cord pH at delivery
4. Neonatal sepsis measured from the Case Report Form collected after delivery
5. Birth weight measured from the Case Report Form collected after delivery
6. Birth trauma measured from the Case Report Form collected after delivery
7. Hypoxic ischaemic encephalopathy/need for therapeutic hypothermia measured from the Case Report Form collected after delivery

Overall study start date
02/10/2021

Completion date
30/08/2022

Eligibility

Key inclusion criteria
1. Nulliparous
2. Aged ≥18 years
3. Gestational age ≥37 weeks
4. Singleton pregnancy
5. Cephalic presentation
6. Intact membrane
7. Reassuring fetal heart tracing
8. Absence of significant contraction ≥2 in 10 min
9. Successful Foley catheter insertion
10. Bishop score ≤5

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
230

Total final enrolment
240

Key exclusion criteria
1. History of Caesarean delivery or hysterotomy/uterine perforation/previous myomectomy
2. Latex allergy
3. Estimated fetal weight <2 kg or >4 kg
4. Placenta previa including minor previa
5. Major fetal malformations
6. Contraindication for vaginal delivery
7. Suspected COVID-19 infection or COVID-19 positive

Date of first enrolment
13/01/2022

Date of final enrolment
23/08/2022

Locations

Countries of recruitment

Malaysia

Study participating centre
University Malaya Medical Centre
Lembah Pantai
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Sponsor information

Organisation
University Malaya Medical Centre

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Sponsor type
Hospital/treatment centre

Website
http://www.ummc.edu.my/#

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, UM

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Malaysia

Results and Publications

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

Intention to publish date
30/08/2023

Individual participant data (IPD) sharing plan
The raw data generated during and/or analysed during the current study are/will be available upon request from Umadevi Appadurai (a.umadevi@ummc.edu.my)

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1.0	02/10/2021	06/01/2022	No	Yes
Results article		17/09/2023	05/02/2025	Yes	No