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Placing the Foley balloon catheter adjacent to the inner portion of the neck of the womb to induce labour in women at their first delivery followed by waiting in the hospital or at home

Submission date
14/05/2024

Recruitment status
No longer recruiting

Registration date
22/05/2024

Overall study status
Completed

Last Edited
20/05/2024

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
In the United Kingdom, the rate of induction of labour (IOL) has increased from 18.3% in 1989-90 to 34.4% by 2020-2, indicating that IOL is increasingly common. In about 70% of IOL cases, mechanical or pharmacological intervention is needed to ripen (open up) the closed cervix. For patients undergoing their first delivery and whose cervix is unripe, the time from induction to birth takes longer and their risk of needing a caesarean is higher. Balloon catheters for IOL are recommended by the WHO (World Health Organisation). They lead to fewer problems for the baby as they usually do not cause contraction pain as they ripen the cervix and are suitable for outpatient use. Available evidence shows that outpatient (with some of the initial ripening time spent at home) IOL is as effective and safe as inpatient (the whole time from the start of the process spent in hospital) IOL. Mothers' satisfaction is also similar with either inpatient or outpatient IOL as a method but the amount of evidence is limited at present. Currently, inpatient Foley balloon IOL is the usual care at the Department of Obstetrics and Gynecology, Faculty of Medicine, University Malaya, Malaysia. The WHO and international experts consider women's experience during childbirth as a critical aspect of high-quality care during childbirth. It is important to explore ways in which the IOL may be managed as acceptably for women as possible. Satisfaction of outcome arising from choice is strongly linked to the process involved in making the choice and if the outcome is positive. However, the impact when patients exercise their free will and make a choice about their care, on their eventual satisfaction with that care, compared to when the same care is delivered as part of standard practice (without conscious selection), has not been explored in a clinical study. This study evaluates in-hospital compared to at-home Foley ripening for labour induction and the impact when patients are allowed to choose or when they are randomly assigned to hospital or at-home IOL.

Who can participate?
Adult women scheduled Foley balloon labour induction

What does the study involve?
This study involves an assessment of mothers' satisfaction based on exposure to in-hospital or at-home IOL and also of the role that maternal choice may play in decision-making in impacting maternal satisfaction with labour induction.

About half of those participating who accept to be assigned to one of the two trial interventions (only after a successful Foley balloon insertion) of
1. Remaining in the hospital to passively wait for 24 hours for the cervix to ripen (partially open) before further assessment
If not spontaneously expelled before 24 hours, the balloon will be removed to assess that the cervix sufficiently ripened for amniotomy
OR
2. Going home to passively wait for 24 hours for the cervix to ripen before returning to the hospital at 8 am the following day for an assessment
A written instruction leaflet will be provided in the event of anticipated developments at home that would require an earlier return to the hospital. In the hospital, if not spontaneously expelled, the balloon will be removed to assess that the cervix sufficiently ripened for amniotomy

About half of those participating who expressed a preference will choose (after a successful Foley balloon), by their own will

1. Remain in the hospital to passively wait for 24 hours for the cervix to ripen (partially open) before further assessment
If not spontaneously expelled before 24 hours, the balloon will be removed to assess that the cervix sufficiently ripened for amniotomy
OR
2. Go home to passively wait for 24 hours for the cervix to ripen before returning to the hospital at 8 am the following day for an assessment

A written instruction leaflet will be provided in the event of anticipated developments at home that would require an earlier return to the hospital. In the hospital, if not spontaneously expelled, the balloon will be removed to assess that the cervix sufficiently ripened for amniotomy

What are the possible benefits and risks of participating?
Mothers' satisfaction with the IOL may or may not be higher as a result of in-hospital vs. at-home Foley IOL (current limited evidence suggests they will be similar). Mothers' satisfaction also may or may not be higher as being able to choose in-hospital vs. at-home Foley IOL. In-hospital IOL may be quicker to birth from insertion of the Foley balloon, however, in contrast, the total time spent in the hospital from Foley balloon insertion to birth may be shorter because some of the time is spent at home.

Major complications such as caesarean birth or the baby being born in a poor condition arising from the interventions are not anticipated, as guided by the available data.

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?
October 2023 to April 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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Public, Scientific, 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
Inpatient vs outpatient Foley catheter induction in nulliparas: a pragmatic randomized controlled trial

Study objectives
Following placement of the Foley balloon for cervical ripening in the induction of labour of women at their first delivery, 1) waiting in the hospital or at home for up to 24 hours, 2) as randomly assigned or by maternal choice, both options will affect maternal satisfaction of their labour induction experience.

The hypotheses are:
1. Inpatient vs outpatient will result in higher maternal satisfaction with the Foley balloon IOL
2. By choice vs as randomised will result in higher maternal satisfaction with the Foley balloon IOL
3. Inpatient by choice vs. inpatient as randomized will result in higher maternal satisfaction with the Foley balloon IOL
4. Outpatient patient by choice vs. outpatient as randomized will result in higher maternal satisfaction with the Foley balloon IOL

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 12/05/2024, University of Malaya Medical Centre Medical Research Ethics Committee (2nd floor, Kompleks Pendidikan Sains Kejururawatan, Pusat Perubatan Universiti Malaya, 59100, Malaysia; +603-79493209/2251/8473/4656; ummc-mrec@ummc.edu.my), ref: 2024221-13445

Study design
Single-centre parallel-design pragmatic randomized controlled trial study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital, Medical and other records

Study type(s)
Treatment, Efficacy

Participant information sheet
Not available in web format, please use the contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Foley balloon labour induction

Interventions
All nulliparous women presenting at the induction facility of our centre for a planned induction of labour will be assessed for trial eligibility and will be counseled about this study. The patient information sheet will provided, and oral queries encouraged and responded to by the care provider doing the recruitment. Informed written consent will be obtained from all participants.

About half of those participating who accept will be randomised to one of the two trial interventions (only after a successful Foley balloon insertion) of
1. Remaining in the hospital to passively wait for 24 hours for the cervix to ripen (partially open) before further assessment
If not spontaneously expelled before 24 hours, the balloon will be removed to assess that the cervix sufficiently ripened for amniotomy
OR
2. Going home to passively wait for 24 hours for the cervix to ripen before returning to the hospital at 8 am the following day for an assessment
A written instruction leaflet will be provided in the event of anticipated developments at home that would require an earlier return to the hospital. In the hospital, if not spontaneously expelled, the balloon will be removed to assess that the cervix sufficiently ripened for amniotomy

About half of those participating who expressed a preference will choose (after a successful Foley balloon), by their own will
1. Remain in the hospital to passively wait for 24 hours for the cervix to ripen (partially open)

before further assessment
If not spontaneously expelled before 24 hours, the balloon will be removed to assess that the cervix sufficiently ripened for amniotomy
OR
2. Go home to passively wait for 24 hours for the cervix to ripen before returning to the hospital at 8 am the following day for an assessment
A written instruction leaflet will be provided in the event of anticipated developments at home that would require an earlier return to the hospital. In the hospital, if not spontaneously expelled, the balloon will be removed to assess that the cervix sufficiently ripened for amniotomy

Standard induction care will be applied at all times. When the cervix has ripened, amniotomy and starting titrated oxytocin infusion in furtherance of achieving labour and birth will be performed.

Randomisation is through the opening of the lowest number, sealed and opaque envelope that is available for the latest recruit. The randomisation sequence will be generated by an online randomiser in random blocks of 4 or 8 by an investigator who is not involved in trial enrolment. Blinding is not feasible due to the nature of the intervention and the design of the study.

During the hospital stay, participants will receive standard care including periodic monitoring of the mother and baby, indicated prophylactic measures and treatments for induction, labour and delivery, arrangements for hospital discharge and postpartum follow-up.

Women will be positioned in the dorsal lithotomy position. A Foley catheter size 16F is introduced through the outer cervical canal using either the digital or speculum method (at the discretion of the introducer). Once the tip of the catheter passes the internal os, the catheter will be inflated with 60 mL of water and then retracted so that the balloon rests on the cervical os and the external end of the Foley catheter will be taped without tension to the medial aspect of the women’s thigh. Fetal monitoring will be performed immediately after the inflation of the balloon catheter.

Randomisation will only be carried out once the catheter is in situ and post-foley catheter insertion CTG is normal.

Intervention Type
Procedure/Surgery

Primary outcome measure
The following maternal satisfaction outcomes with the Foley balloon labour induction will be measured using an 11-point (0-10) numerical rating scale (NRS) before hospital discharge:
1. Inpatient vs. outpatient
2. By choice vs randomised
3. Inpatient by choice vs. inpatient as randomised
4. Outpatient patient by choice vs. outpatient as randomised

Secondary outcome measures
Maternal outcomes:
1. If they would recommend their intervention of inpatient or outpatient to a friend measured using a Likert scale (5-grade) response (assessed before hospital discharge) to (strongly agree to strongly disagree) before hospital discharge
2. Cervical ripening measured using the Bishop score before and after the intervention

3. Use of additional method for cervical ripening measured using data collected in medical records at the end of the study
4. Time to delivery after Foley removal/expulsion measured using data collected in medical records at the end of the study

5. Mode of delivery measured using data collected in medical records at the end of the study:
5.1. Spontaneous vaginal
5.2. Vacuum
5.3. Forceps
5.4. Caesarean section

The following outcomes are measured using data collected in medical records at the end of the study:
6. Indication for operative delivery
7. Duration of oxytocin infusion
8. Blood loss during delivery
9. Third- or fourth-degree tear
10. Maternal infection
11. Use of regional analgesia in labour (epidural)
12. Length of hospital stay
13. ICU admission
14. Cardiopulmonary arrest
15. Needing hysterectomy

16. Maternal satisfaction with the Foley balloon IOL: choice vs randomised measured using an 11-point 0-10 visual numerical rating scale (NRS)
Neonatal outcomes

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

Overall study start date
01/10/2023

Completion date
01/04/2025

Eligibility

Key inclusion criteria
1. Scheduled Foley balloon labour induction
2. The patient has transport available and lives within 30 minutes of the hospital
3. The patient has a functional telephone
4. Ability to communicate in English or Malay

5. Term ≥ 37 weeks gestation
6. Singleton pregnancy
7. Nulliparous (no prior pregnancy ≥ 22 weeks)
8. Cephalic presentation
9. Reassuring fetal heart rate monitoring
10. Intact membranes
11. Unfavourable cervix (Bishop score ≤ 6)
12. Successful Foley balloon insertion

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
45 Years

Sex
Female

Target number of participants
252

Key exclusion criteria
1. Patient that contraindicated for vaginal delivery (eg: Placenta Previa, non-cephalic presentation)
2. Latex allergy
3. Fetal anomaly
4. Regular contraction of more than 2 in 10 minutes

Date of first enrolment
15/06/2024

Date of final enrolment
15/03/2025

Locations

Countries of recruitment
Malaysia

Study participating centre
University Malaya Medical Centre
Lembah Pantai
Kuala Lumpur

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Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

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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
30/11/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request. Available for institutional review board-approved individual patient data meta-analysis 12 months after publication

IPD sharing plan summary
Available on request