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Labour induction with the Foley balloon at home or in hospital and the impact of women's ability to choose at home or in-hospital labour induction

Submission date
06/06/2024

Recruitment status
No longer recruiting

Registration date
11/06/2024

Overall study status
Completed

Last Edited
15/07/2024

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
Induction of labour (IOL) is common. United Kingdom national data shows the IOL rate had increased from 18.3% in 1989-90 to 34.4% by 2020-21. About 70% of IOL require the closed neck of the womb (cervix) to be slightly opened (ripened) before the forewaters can be accessed to be broken and in turn for the oxytocin drip to be started to initiate labour contraction pains to achieve the full opening needed for normal vaginal birth.
Opening up the cervix with a catheter (tube) inserted through the vagina and neck of the womb, for the balloon to be inflated and placed in the lower womb, is usually painless. IOL using a balloon leads to fewer complications for the baby with a similar cesarean delivery and maternal complication rate compared to the use of using drugs like prostaglandins administered into the vagina. The lack of pain and its good safety profile make a balloon particularly suited for use to ripen the neck of the womb in IOL.
A meta-analysis that takes into account all suitable studies of at-home compared to in-hospital IOL finds no differences in delivery method, adverse outcomes or resource use but these findings are not considered conclusive. Hence these interventions that have broadly similar clinical performance are a good basis for a study to evaluate the impact of patient choice compared to assignment.
Maternal satisfaction is an important healthcare outcome described by the WHO as a critical aspect of ensuring high-quality labour and childbirth care. The contribution of patient choice in their treatment (specifically in this study, the decision to go home or remain in hospital for the initial 24 hours after Foley balloon insertion) to maternal satisfaction has not been explored.
In a survey of 50 women admitted for IOL, 52% would consider participation in this type of study. Of women prepared to participate, 54% will choose in-hospital IOL, 23% will choose at-home IOL and 23% have no preference and would be prepared to be randomly allocated to either in-hospital or at-home Foley balloon IOL. Patients clearly have different opinions about these aspects of IOL management on being informed that these interventions are likely to have broadly similar clinical performance.

Who can participate?
Patients aged 18 years and over who have at least one previous vaginal birth attending for their planned labour induction and whose labour induction is by the Foley balloon

What does the study involve?
The study is about evaluating two separate issues. First, to compare at-home to in-hospital induction of labour using the Foley balloon. Second, to evaluate the impact choice of choice by comparing patients who choose the intervention as personally preferred to when the intervention was randomly allocated as the patients did not have a preference.
The study permits after informed consent for patients to make their own choices about at-home or in-hospital Foley labour induction, and in patients who have no preference to allow for this aspect of their labour induction to be randomly assigned.
Standard labour induction care will otherwise be provided to all patients. Care providers will have complete discretion to make all clinical decisions in consultation with the patients and in the patient's best interest.

What are the possible benefits and risks of participating?
Major complications are not anticipated. It is possible that following catheter dislodgement or after removal, the cervix may not be sufficiently opened for breaking of the forewaters. In this instance other methods for ripening are available from the care provider. Significant benefits should not be expected. Mothers' satisfaction may or may not be higher with the various options studied.

Where is the study run from?
University Malaya Medical Center (Malaysia)

When is the study starting and how long is it expected to run for?
September 2023 to May 2025

Who is funding the study?
University Malaya Medical Center (Malaysia)

Who is the main contact?
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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 balloon labour induction in multiparas: a pragmatic randomized controlled trial

Study objectives
Induction of labour with the Foley balloon:
1. At home (for up to 24 hours if no interim events, before readmission for labour and delivery) compared to in hospital (until after delivery)
2. Whereby the labour induction location is chosen by the women compared to randomly assigned
3. At home by women's choice compared to at home as randomly assigned
4. In hospital by women's choice compared to in hospital as randomly assigned
will result in higher maternal satisfaction

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 07/06/2024, University of Malaya Medical Center - Medical Research Ethics Committee (2nd Floor, Kompleks Pendidikan Sains Kejururawatan, Pusat Perubatan Univeristi Malaya, Kuala Lumpur, 59100, Malaysia; +60 (0)379493209; ummc-mrec@ummc.edu.my), ref: 2024224-13459

Study design
Single-center parallel-design pragmatic randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home, Hospital, University/medical school/dental school

Study type(s)
Other, Quality of life

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

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

Interventions

Recruitment:
Patients admitted for their planned labour induction will be screened for eligibility. Potentially eligible patients will be approached, provided with the patient information sheet, and verbally engaged on trial aspects by the care provider for trial participation. Informed written consent will be obtained from all participants. The final inclusion criterion is the successful placement of the Foley balloon.

Randomisation and allocation:
After the successful placement of the Foley balloon, patients will be asked if they choose to go home for up to 24 hours, stay in hospital until after delivery or they have no preference and are prepared to be randomly assigned to going home or stay in hospital. Patients choosing to go home or remain in hospital will be accommodated.

Patients who do not express a preference and are prepared to accept randomisation will be randomised by opening the lowest number opaque sealed envelope still available to reveal their allocated trial intervention. The randomisation sequence will be generated using the online site https://www.sealedenvelope.com by an investigator not involved in trial recruitment. Numbered, sealed and opaque envelopes containing the randomly allocated trial intervention will be prepared. Inappropriately opened envelopes will be discarded and the event recorded.

Interventions:
1. Participant chooses to go home for the initial 24 hours after Foley balloon insertion
2. Participant chooses in-hospital management until delivery
3. Participant randomised to
3.1. To go home for the initial 24 hours after Foley balloon insertion
3.2. In-hospital management until delivery

In-hospital patients will be managed with our standard Foley induction care protocol (in-hospital Foley induction management is the default on offer at our centre). The Foley balloon is left passively in place for 24 hours before removal to check for a ripened cervix, the onward breaking of the forewaters and starting of an oxytocin drip to initiate labour contractions. If the balloon is spontaneously expelled before 24 hours, the patient is examined without delay to check for a ripened cervix.

For patients going home, they will be informed that the Foley balloon may spontaneously dislodge from the vagina before their scheduled return to hospital in the morning. might occur while at home. They were asked to record the time of balloon expulsion. An instruction sheet will be provided on interim events for which they should return to the hospital without delay for assessment. If the Foley balloon remains uneventfully in place, they will be asked to come back the next day morning at 8 am for the planned removal of the Foley catheter and vaginal assessment for a ripened cervix.

Care providers always have full discretion in deciding care in the patient’s best interest and in accordance with the institutional induction of labour care protocol during the trial.

The aim is to recruit:
1. 63 participants who choose to go home for the initial 24 hours after Foley balloon insertion
2. 63 participants who choose in-hospital management until delivery
3. 126 participants who are open to random assignment
3.1. 63 randomised to go home for the initial 24 hours after Foley balloon insertion

3.2. 63 randomised to in-hospital management until delivery
Once the target numbers for each category are achieved, only women prepared to be considered for the remaining open category will be recruited.

Intervention Type
Procedure/Surgery

Primary outcome measure
Maternal satisfaction with their labour induction scored with the 11-point 0-10 visual numerical rating scale in the following settings:
1. At home (for up to 24 hours if no interim events, before readmission for labour and delivery) compared to in hospital (until after delivery)
2. Whereby the labour induction location is chosen by the women compared to randomly assigned
3. At home by women's choice compared to at home as randomly assigned
4. In-hospital by women's choice compared to in-hospital as randomly assigned
Scored with the 0-10 numerical rating scale (NRS) within 24 hours of delivery

Secondary outcome measures
All retrieved from participants' electronic medical records after their hospital discharge:
Based on the core outcome set for trials on induction of labour (CROWN):

Maternal outcomes:
1. Change in bishop score after intervention
2. Use of additional cervical ripening
3. Time to delivery after Foley removal/expulsion
4. Mode of delivery:
4.1. Spontaneous vaginal
4.2. Vacuum
4.3. Forceps
4.4. Caesarean section
5. Indication for operative delivery
6. Duration of oxytocin infusion
7. Blood loss during delivery
8. Third-or fourth-degree tear
9. Maternal infection (temperature ≥38oC from IOL to discharge)
10. Regional analgesia in labour (epidural)
11. Length of hospital stay
12. ICU admission (and indication)
13. Cardiorespiratory arrest
14. Needing hysterectomy

Neonatal outcomes:
15. Apgar score at 1 and 5 minutes
16. NICU admission (and indication)
17. Cord artery pH and base excess
18. Neonatal sepsis
19. Birth weight
20. Birth trauma

21. Hypoxic ischaemic encephalopathy/need for therapeutic hypothermia
22. Before their discharge, participants will be asked to provide a 5-grade Likert scale response on if they will recommend their their Foley catheter IOL to a friend

Overall study start date
15/09/2023

Completion date
31/05/2025

Eligibility

Key inclusion criteria
1. Pregnant women (at least one vaginal delivery ≥24 weeks)
2. Age ≥18 years
3. Gestational age of ≥37 weeks
4. Singleton pregnancy
5. Cephalic presentation
6. Intact membrane
7. Reassuring fetal heart tracing
8. Absence of significant contraction ≥2 in 10 minutes
9. Successful Foley insertion for IOL

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. History of caesarean delivery or hysterotomy/uterine perforation/previous myomectomy
2. Latex allergy
3. Estimated fetal weight less than 2 kg or >4 kg
4. Fetus with anomaly
5. Contraindication for vaginal delivery

Date of first enrolment
01/07/2024

Date of final enrolment
01/03/2025

Locations

Countries of recruitment
Malaysia

Study participating centre
University Malaya Medical Center
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Hospital/treatment centre

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ROR
https://ror.org/00vkrxq08

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Investigator initiated and funded

Funder Name
University Malaya Medical Centre

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
Available for institutional review board approved individual patient data meta-analysis 12 months after publication

IPD sharing plan summary
Available on request