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Placement of the inflated transcervical Foley catheter for 6 compared with 12 hours in labour induction of women with previous childbirth

Submission date
14/01/2022

Recruitment status
No longer recruiting

Registration date
18/01/2022

Overall study status
Completed

Last Edited
16/06/2025

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Approximately 20–25% of pregnant women undergo induction of labour (IOL) for a variety of reasons with many requiring cervical ripening (softening of the cervix necessary for cervical opening) because the cervix is still closed.
Time to delivery from the start of IOL is an important consideration because the longer that takes, usually the risk of caesarean delivery, heavy vaginal bleeding after birth, infections in both mother and baby are higher and mothers' satisfaction with the IOL is reduced.
Mechanical induction particularly with the single-balloon Foley catheter (an inserted tube used to inflate a baloon) is widely used as the primary IOL method. Studies have compared placement for 6 vs 12 hours placement with the use of a double balloon catheter, finding that 6-hour placement results in a quicker delivery.
The aim of the study is to evaluate 6 hours compared to 12 hours placement of the single balloon Foley catheter, solely in women who had previous vaginal childbirth on duration to delivery and maternal satisfaction with the IOL regimen.

Who can participate?
Women at term, scheduled for IOL, aged 18 years and above with prior vaginal childbirth.

What does the study involve?
The Foley catheter is usually inserted through the cervix into the lower womb. The balloon near the tip is then inflated with 80 ml of sterile water. After the Foley catheter balloon has been inflated and retained, the external tubing of the Foley catheter will be taped without tension to the inner aspect of the thigh. Once the Foley balloon is in place and a normal fetal heart rate tracing is obtained, the random allocation of intervention will be carried out. Participants have an equal chance of being assigned to either Foley placement followed by removal at
A) 6 hours or
B) 12 hours
In the interim, management is passive and expectant unless clinical developments warrant intervention.

What are the possible benefits and risks of participating?
A shorter time placement before removal of the Foley catheter may shorten the interval to birth. Apart from the time to birth, the study is not anticipated to materially impact other mother or baby outcomes.
Major complications attributable to the interventions are not anticipated. Despite balloon ripening, most women who have given birth vaginally previously will still require the breaking of waters and also a hormone drip to initiate contractions and start labour.
Participants allocated to 6-hour removal may find that their cervix might not have ripened sufficiently to allow their waters to be broken and further ripening is needed. There are various options available in this situation.

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 2021 to April 2023

Who is funding this study?
Department of Obstetrics and Gynaecology, Faculty of Medicine, University Malaya, 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
2021107-10661

Study information

Scientific Title

6 hours vs 12 hours of Foley's catheter placement for labour induction in multiparous women with unripe cervices: a randomised trial

Acronym
FOLIM

Study objectives
Induction of labour with Foley catheter planned removal at 6 compared to 12 hours will shorten the interval to delivery and increase maternal satisfaction.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 03/01/2022, University of Malaya Medical Centre Medical Research Ethics Committee (Lembah Pantai, 59100 Kuala Lumpur, Malaysia; +60379498473; ummc-mrec@ummc.edu.my), ref: MREC ID: 2021107-10661

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

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
Parous women at term with unripe cervixes and who had Foley catheter inserted trans-cervically and its balloon inflated for induction of labour will be randomized to scheduled catheter removal at
A) 6 hours or
B) 12 hours

After the insertion of the Foley catheter to its scheduled removal, the management is typically passive and expectant. Interim vaginal assessment and tugging of the Foley catheter to expedite expulsion are avoided. However, in the event of strong painful contractions, membrane rupture, vaginal bleeding in excess of a show, non-reassuring fetal status, maternal fever or other

worrisome clinical development, then vaginal assessment, catheter removal, amniotomy, and initiation of titrated intravenous oxytocin infusion may occur as appropriate within the 6- or 12-hours trial intervention periods. If the Foley balloon is spontaneously expelled within the 6- or 12-hours trial intervention periods, standard management to push on with the induction of labour process will occur.

Intervention Type
Procedure/Surgery

Primary outcome measure
Measured after birth:
1. Foley's catheter insertion to delivery interval (min) using patient records
2. Maternal satisfaction with the labour induction process (using an 11-point 0 to 10 visual numerical rating scale)

Secondary outcome measures
Measured using patient records:
Maternal outcomes:
1. Requirement of induction of labour measured by Bishop score before and after intervention
2. Use of additional method for cervical ripening
3. Time to delivery after Foley's catheter removal
4. Mode of delivery
5. Indication for caesarean section
6. Duration of oxytocin infusion
7. Blood loss during delivery
8. Third -or fourth-degree tear
9. Maternal infection before hospital discharge
10. Use of regional analgesia in labour
11. Length of hospital stay (days)
12. ICU admission before hospital discharge
13. Cardiorespiratory arrest before hospital discharge
14. Hysterectomy before hospital discharge

Neonatal outcomes:
1. Apgar score at 1 and 5 minutes
2. NICU admission before hospital discharge
3. Cord pH
4. Neonatal sepsis before hospital discharge
5. Birth weight (kg)
6. Birth trauma
7. Hypoxic ischaemic encephalopathy/need for therapeutic hypothermia before hospital discharge

Overall study start date
14/09/2021

Completion date
01/04/2023

Eligibility

Key inclusion criteria
1. Multiparous women (at least 1 prior vaginal delivery of 24 weeks or more gestation)
2. Age ≥18 years
3. Term pregnancy >36 weeks gestation
4. Singleton pregnancy
5. Cephalic presentation
6. Intact membranes
7. Reassuring fetal heart tracing
8. Absence of significant contraction ≥2 in 10 minutes
9. Successful Foley insertion for IOL
10. Bishop score ≤5

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
220

Total final enrolment
220

Key exclusion criteria
1. History of caesarean delivery, hysterotomy, uterine perforation or myomectomy
2. Latex allergy
3. Estimated Fetal weight <2kg or >4kg
4. Known fetal major malformations
5. Contraindication for vaginal delivery
6. Patient who is suspected to have Covid 19 infection or SARS-CoV-2 positive

Date of first enrolment
24/01/2022

Date of final enrolment
30/04/2022

Locations

Countries of recruitment
Malaysia

Study participating centre
University Malaya Medical Center
Lembah Pantai
Kuala Lumpur
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Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

Website
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ROR
https://ror.org/00vkrxq08

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Malaya Medical Centre

Results and Publications

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

Intention to publish date
01/09/2023

Individual participant data (IPD) sharing plan
The raw data generated during and/or analyzed during the current study are/will be available upon request from Nadiah Kamarudzman (nadiah.k@ummc.edu.my) subject to the approval of the institutional review board.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 3.0	07/10/2021	18/01/2022	No	Yes
Protocol file	version 2.0	13/12/2021	18/01/2022	No	No
Participant information sheet	version 3.1	23/01/2022	24/01/2022	No	Yes
Results article		27/08/2023	16/06/2025	Yes	No