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Tugging the Foley catheter (a balloon inflated inside the womb) every three hours in the labour induction of women in their first birth

Submission date
19/02/2023

Recruitment status
No longer recruiting

Registration date
02/03/2023

Overall study status
Completed

Last Edited
07/03/2025

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[X] 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) occurs in 20–25% of births. The Foley catheter balloon is used (first choice in UMMC) to open (ripen) the closed cervix (neck of the womb) as the first step in labour induction. The process of ripening with the Foley balloon is typically not painful. After the cervix has opened sufficiently (usually 3 cm), the next steps are for the forewaters to be broken and the oxytocin drip started to initiate contractions (labour pain) leading to labour and birth.

The usual practice is to leave the Foley balloon (inflated to 30 ml) in place passively (no tugging) for 12 hours after insertion, before deflating and removing it to check if the cervix has opened. Oftentimes the balloon can pass through the sufficiently opened cervix after only a few hours but is retained in the upper vagina without causing discomfort. This scenario is more likely to happen in nulliparous women (in their first labour) as their vaginal muscle tone is stronger so spontaneous balloon expulsion is less likely or slower to occur.

We think that tugging on the catheter once every 3 hours to check if the balloon is just sitting comfortably in the vagina waiting to come out will allow for the earlier discovery that the cervix is open and ready for the forewaters to be broken, oxytocin drip to be started and hence for birth to occur sooner when compared to the standard practice of passively waiting up to 12 hours whilst waiting for spontaneous expulsion.

We plan to compare tugging at 3 hourly intervals vs standard management (no tugging) of the Foley catheter in the labour induction of nulliparous (first labour) women to evaluate their impact on the time interval from start of induction to delivery and maternal satisfaction with the birth process after their labour induction.

Who can participate?
Pregnant women aged 18 years or older, who are expecting their first child, and require scheduled labour induction.

What does the study involve?
The Foley catheter is usually inserted digitally (a vaginal speculum can be used if digital insertion is unsuccessful) through the cervix into the lower womb. The balloon near the tip is then inflated with 30 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 your thigh. You can move around freely and perform bodily functions without any impairment.
Once the Foley balloon is in place and the baby's status is confirmed to be reassuring (by cardiotocograph) only then the random allocation will be carried out. You have an equal chance of being assigned to either 1) Tugging of the Foley every 3 hours or 2) Standard management (no tugging) during the 12 hours of placement.

What are the possible benefits and risks of participating?
Benefits
Three hourly tugging of the Foley catheter before may shorten the interval to birth and increase maternal satisfaction with their birth process after labour induction. The study intervention is not anticipated to materially impact on other mother or baby outcomes.
Risk
Major complications are not anticipated. The Foley catheter tugging may be uncomfortable or even painful (tugging will cease on participants' instruction on the perception of pain). It is possible that following catheter dislodgement after tugging (or even removal after standard 12 hours) the cervix may not be sufficiently opened for breaking of the forewaters. In this instance, other options (including reinserting the Foley again) for ripening are available from your care provider to continue with the labour induction.

Where is the study run from?
Labour ward and antenatal ward of Universiti Malaya Medical Centre (Malaysia)

When is the study starting and how long it is expected to run for?
November 2022 to December 2024

Who is funding the study?
Department of Obstetrics and Gynaecology, PPUM, Universiti Malaya Medical Centre (Malaysia)

Who is the main contact?
Dr Muhamad Aznor Aqwa Bin Azman, aznor_aqwa92@yahoo.com

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Additional identifiers

Protocol serial number
20221230-11900

Study information

Scientific Title
Tugging the foley catheter every three hours in the labour induction of nulliparous women: a randomised trial

Acronym
TOFIL

Study objectives
We hypothesise that the tugging of the Foley catheter every 3 hours will:
1. Shorten the induction to delivery interval
2. Increase maternal satisfaction with the labour induction

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/01/2023, Medical Research Ethics Committee (formerly known as Medical Ethics Committee, University of Malaya Medical Centre, Lembah Pantai, 59100 Kuala Lumpur, Malaysia; +60 3-79493209/2251; ummc-mrec@ummc.edu.my), ref: 20221230-1190

Primary study design
Interventional

Study design
Interventional randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Nulliparous women undergoing induction of labour with Foley catheter

Interventions
Women randomised to :
3 hourly tugging, care providers will be instructed to “tug” the external end of the foley’s catheter to a level of just below patient discomfort and to sustain the tug for at least 30 second to gauge for resistance to descend every three hours. If there is a comfortable descent, the balloon can be retrieved
OR
The control arm will receive standard passive placement of their Foley without tugging

The Foley catheter will be removed at 12 hours after placement in both arms if not previously spontaneously expelled or tugged-out.

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. The randomisation sequence will be generated using a random number generator in random blocks of 4 or 8 by an investigator who is not involved in recruitment.

Intervention Type

Other

Primary outcome(s)
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)

Key secondary outcome(s)
Measured using patient records:
Maternal outcomes:
1. 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. Blood loss during delivery
7 Third -or fourth-degree tear
8. Maternal infection before hospital discharge
9 Use of regional analgesia in labour
10. Length of hospital stay (days)
11. ICU admission before hospital discharge
12. Cardiorespiratory arrest before hospital discharge
13. 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

Completion date
17/12/2023

Eligibility

Key inclusion criteria
1. Nulliparous
2. Age ≥18 years
3. Gestational age of ≥37 weeks
4. Singleton pregnancy
5. Cephalic presentation
6. Intact membrane
7. Reassuring fetal heart rate tracing
8. Absence of significant contraction ≥2 in 10 minutes
9. Successful Foley insertion for induction of labour

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Female

Key exclusion criteria
1. History of uterine perforation/ previous myomectomy
2. Latex Allergy
3. Estimated fetal weight < 2 kg or > 4 kg
4. Known major fetal malformations
5. Contraindication for vaginal delivery
6. Patient who is suspected COVID 19 infection or COVID 19 positive

Date of first enrolment
06/03/2023

Date of final enrolment
13/12/2023

Locations

Countries of recruitment
Malaysia

Study participating centre
Universiti Malaya Medical Centre (UMMC)
Universiti Malaya Medical Centre
Lembah Pantai
Kuala Lumpur
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Sponsor information

Organisation

University Malaya Medical Centre

ROR
https://ror.org/00vkrxq08

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Malaya Medical Centre

Results and Publications

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 Muhamad Aznor Aqwa Azman (aznor.aqwa@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 1	14/12/2022	20/02/2023	No	Yes
Protocol file			17/07/2023	No	No