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Tugging the balloon every three hours to check for dislodgement during the Foley catheter labour induction of women who had previously given birth

Submission date
15/11/2022

Recruitment status
No longer recruiting

Registration date
24/11/2022

Overall study status
Completed

Last Edited
07/04/2025

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 is very common, involving about a quarter of pregnancies at term. The single-balloon Foley catheter is widely used as the primary method for labour induction when the neck of the womb (cervix) is unripe for the mechanical ripening of the cervix due to its low cost and low risk of overstimulating the womb (uterus) compared to drugs like prostaglandins and oxytocin. After the catheter has been placed through the cervix into the lowest part of the uterus and its balloon inflated to 30 ml with water, the standard practice is to wait up to 12 hours for the balloon to be spontaneously expelled out of the vagina after the cervix has ripened (partially opened to allow the balloon to pass through). After balloon expulsion, the forewater is broken and oxytocin drip started to initiate contraction pain for the labour to proceed. After the cervix has opened sufficiently to allow passage of the Foley balloon, the spontaneous passage down the vaginal leading to the expulsion of the balloon can take time (possibly hours). This delay in the breaking of the forewaters and the start of the oxytocin, delay labour contraction pain and delivery. By tugging the Foley catheter periodically every three hours to check for balloon dislodgement through the cervix, any dislodgement can be detected earlier, allowing for the timely breaking of the forewaters and start of the oxytocin drip hastening labour contraction pain and hence, expediting delivery. We anticipate that periodic gentle tugging will be well tolerated. A lengthy labour induction process adversely impacts maternal satisfaction and can increase healthcare costs.

Who can participate?
Labouring adult women who are being induced and have had a successful Foley catheter insertion

What does the study involve?
Following the placement of the Foley catheter balloon in the cervix for labour induction, the

patients will either be in a group that receives tugging of the balloon every three hours to check for dislodgement or standard care (no tugging) while awaiting spontaneous expulsion of the Foley balloon.

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

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

When is the study starting and how long is it expected to run for?
May 2022 to August 2023

Who is funding the study?
UMMC (Malaysia)

Who is the main contact?
1. Dr Noor Fadzliana Binti Mohd Zin (Affiliation Medical Officer Obstetrics and Gynaecology) (Malaysia), fadzliana_86@yahoo.com
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Public, Principal investigator

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Additional identifiers

Protocol serial number
202298-11524

Study information

Scientific Title
Tugging the balloon every three hours during the Foley catheter labour induction of multiparas: a randomised trial

Acronym
TugFoleyIOL

Study objectives
We hypothesise that tugging of the Foley catheter balloon every three hours compared to standard care (non tugging) after Foley insertion for the labour induction of multiparas with unripe cervixes will:
1. Shorten the induction to delivery interval and
2. Improve maternal satisfaction

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 19/10/2022, Medical Research and Ethics Committee University Malaya Medical Center (University Malaya Medical Center, Jalan University, Lembah Pantai, 59100, Kuala Lumpur, Malaysia; +603-79494422; ummc@ummc.edu.my), ref: 202298-11524

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Induction of labour in multiparas with unripe cervixes using Foley catheter balloon

Interventions
The participant information sheet will be given to all potential recruits and any inquiries by the participants will be answered by the recruiting care provider. Written consent will be obtained from all participants. Randomisation will be performed and the intention-to-treat patient population revealed only after successful Foley insertion. Randomisation will be performed 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. Blinding is not possible due to the nature of the intervention.

Following the transcervical placement of the Foley catheter balloon for labour induction, the patient will be randomised into two trial arms:
1. Tugging of the balloon every three hours to check for dislodgement or
2. Standard care (no tugging) while awaiting spontaneous expulsion of Foley balloon

Intervention Type
Procedure/Surgery

Primary outcome(s)
Induction to delivery interval measured using the time from the insertion of the Foley catheter until delivery, at a baseline of 48 hours

Key secondary outcome(s))
Maternal satisfaction with the birth process after labour induction measured using a questionnaire, 24 hours after the end of the trial

Completion date
03/08/2023

Eligibility

Key inclusion criteria
1. Multiparous women (at least 1 vaginal delivery ≥ 24 weeks)
2. Age ≥ 18 years
3. Gestational age ≥ 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 catheter insertion for induction of labour

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Total final enrolment
220

Key exclusion criteria
1. History of caesarean delivery, hysterotomy, uterine perforation or previous myomectomy
2. Latex allergy
3. Estimated fetal weight < 2kg or > 4kg
4. Known major fetal malformations
5. Contraindications for vaginal delivery
6. Patient who is suspected of harbouring COVID-19 infection or is COVID-19 positive

Date of first enrolment
07/12/2022

Date of final enrolment
01/08/2023

Locations

Countries of recruitment
Malaysia

Study participating centre
University Malaya Medical Center
University Malaya
Jalan Profesor Diraja Ungku Aziz
59100
Malaysia
59100

Sponsor information

Organisation
University of Malaya

ROR
https://ror.org/00rzspn62

Funder(s)

Funder type
University/education

Funder Name
Universiti Malaya

Alternative Name(s)
University of Malaya, University Malaya, Malayan University, King Edward VII College of Medicine, Raffles College, University of Malaya in Singapore, , , , UM

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Malaysia

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Noor Fadzliana Binti Mohd Zin (fadzliana_86@yahoo.com).

Added 24/09/2024:
Participant data analysed are available upon reasonable request for board-approved individual participant data meta-analysis 12 months after publication from the corresponding author

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	14/09/2022	23/11/2022	No	Yes
Protocol file	version 1.0	14/09/2022	23/11/2022	No	No