

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

<b>Submission date</b> 19/02/2023	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 02/03/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 07/03/2025	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> 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](mailto:aznor_aqwa92@yahoo.com)

## Contact information

**Type(s)**

Principal Investigator

**Contact name**

Dr Muhamad Aznor Aqwa Azman

**ORCID ID**

<https://orcid.org/0000-0001-8054-8460>

**Contact details**

No. 15, Jalan Alam Suria 16/73  
Seksyen 16  
Bandar Puncak Alam  
Malaysia  
42300  
+60 1110165717  
aqwaazman@um.edu.my

**Type(s)**

Principal Investigator

**Contact name**

Prof Peng Chiong Tan

**ORCID ID**

<http://orcid.org/0000-0001-8713-6581>

**Contact details**

Pusat Perubatan Universiti Malaya  
Jln Profesor Diraja Ungku Aziz  
Kuala Lumpur  
Malaysia  
59100  
+60 12-3052970  
tanpengchiong@yahoo.com

**Type(s)**

Principal Investigator

**Contact name**

Prof Mukhri Hamdan

**ORCID ID**

<http://orcid.org/0000-0002-1006-2614>

**Contact details**

Pusat Perubatan Universiti Malaya  
Jalan Profesor Diraja Ungku Aziz  
Kuala Lumpur  
Malaysia  
59100  
+60 123615253  
mukhri@ummc.edu.my

## **Additional identifiers**

**EudraCT/CTIS number**

Nil known

**IRAS number**

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

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

**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**

See study outputs table

**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 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. 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

**Overall study start date**

01/11/2022

**Completion date**

17/12/2023

## Eligibility

**Key inclusion criteria**

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

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Female

**Target number of participants**

260

**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

Malaysia

59100

**Sponsor information****Organisation**

University Malaya Medical Centre

**Sponsor details**

Department of Obstetrics and Gynaecology

Jalan Profesor Diraja Ungku Aziz

Kuala Lumpur

Malaysia

59100

+60 379494422

ummc@ummc.edu.my

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.ummc.edu.my/>

**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

13/12/2025

## 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?
<a href="#">Participant information sheet</a>	version 1	14/12/2022	20/02/2023	No	Yes
<a href="#">Protocol file</a>			17/07/2023	No	No