ISRCTN16633990 https://doi.org/10.1186/ISRCTN16633990

Tugging the foley's catheter every three hours in the labor induction of women with a previous caesarean section

Submission date
27/03/2023

Recruitment status
No longer recruiting

Registration date
28/03/2023

Overall study status
Completed

Last Edited
17/09/2024

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
About 25% of pregnant women have their labour induced or started early for various reasons. Induction of labour after one previous cesarean is considered a high-risk procedure as the process has a significant risk of not being successful (25-50%) and a caesarean section is then needed. There is also the small risk of uterine scar rupture (about 0.5%). In well-motivated women, it is an accepted practice and considered safe when conducted in a well-resourced. If vaginal birth is achieved, both mother and baby tend to have better outcomes compared to a planned repeat caesarean but the outcome is generally the least favourable if the induction was not successful.

A mechanical method for cervical ripening at labour induction is widely used when the cervix is still closed or minimally open (unfavourable or unripe) as this method to open the cervix for the first 3-5 cm (ripening) can be achieved typically without significant pain (contractions). Once the cervix is opened to at least 3 cm, the forewater can be easily broken and the oxytocin hormone started as needed to bring on the necessary contractions to achieve the full cervical opening and ultimately the baby to be delivered normally.

The Foley catheter (a thin rubber tube with an inflatable balloon at the end) is a popular mechanical method of cervical ripening as it is effective. Complications to the baby can be fewer as this method typically does not cause contractions during ripening. The balloon can be easily inserted through feel by hand or through a speculum (a device inserted into the vagina which when opened allows for the neck of the womb to be seen) under direct view and the tube to be inserted this way. The tube is passed through the opening of the neck of the womb just into the lower womb and the balloon is then inflated to 30 ml and then pulled back slightly to rest on the inner portion of the neck of the womb. The outer end of this tube is taped to the woman’s thigh usually without tension to the balloon. This balloon placement starts the process for the neck of the womb to soften and open.

Who can participate?
Women aged 18 years or older who have previously had a caesarean section and are due to give birth.

What does the study involve?
Participants will be randomly allocated to receive either:
1. During Foley balloon cervical ripening, the catheter will be tugged intermittently, every three hours to check for dislodgement (indicating a ripened cervix) following which the balloon will be retrieved and amniotomy and titrated oxytocin infusion can commence expediting labour and delivery
OR
2. Standard care during Foley balloon cervical ripening whereby the Foley balloon will be passively left in place (no tugging) to await spontaneous expulsion. Following spontaneous expulsion with the cervix ripened, amniotomy and titrated oxytocin infusion can commence expediting labour and delivery

Standard care during labour induction, labour, delivery and after delivery will be provided to all participants

What are the possible benefits and risks of participating?
We anticipate a shorter time to birth and higher maternal satisfaction with tugging compared to standard care. The risk of tugging would be that it maybe uncomfortable, even painful. The tugging will cease if the pain is felt. Also, it is possible that tugging will dislodge the balloon through a borderline opened neck of the womb which is just not opened enough for the waters to be broken, in which case the Foley catheter needs to be re-inserted or another method used to ripen the cervix further.

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

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

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

Who is the main contact?
Dr Yunesh Krishnan, yunesh@ummc.edu.my

Contact information

Type(s)
Principal investigator

Contact name
Dr Yunesh Krishnan

Contact details
University Malaya
Jalan Profesor Diraja Ungku Aziz
Lembah Pantai

Kuala Lumpur
Malaysia
59100
+60 11-33275017
yunesh@ummc.edu.my

Type(s)
Scientific

Contact name
Prof Tan Peng Chiong

Contact details
University Malaya
Jalan Profesor Diraja Ungku Aziz
Lembah Pantai
Kuala Lumpur
Malaysia
59100
+60 3-79492059
pctan@um.edu.my

Type(s)
Scientific

Contact name
Prof Aizura Syafinaz Ahmad Adlan

Contact details
University Malaya
Jalan Profesor Diraja Ungku Aziz
Lembah Pantai
Kuala Lumpur
Malaysia
59100
+60 379492049
aizura@um.edu.my

Type(s)
Public

Contact name
Dr Yunesh Krishnan

Contact details
University Malaya
Jalan Profesor Diraja Ungku Aziz
Lembah Pantai
Kuala Lumpur
Malaysia
59100

+60 11-33275017
yunesh@ummc.edu.my

Additional identifiers

Protocol serial number
MECID.No 2023125-12032

Study information

Scientific Title
Tugging the foley's catheter every three hours in the labor induction of women with a previous caesarean section: A randomised trial

Study objectives
Tugging the foley's catheter to check for dislodgement (indicating cervical ripening) every three hours will shorten the induction to delivery interval and increase maternal satisfaction with the birth process

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved on 15/03/2023, Medical Research Ethics Committee (University of Malaya Medical Centre, Lembah Pantai, 59100 Kuala Lumpur, Malaysia; +60 3-79493209/2251; ummc-mrec@ummc.edu.my), ref: 2023125-12032

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Women who had a prior caesarean delivery undergoing cervical ripening in labour induction

Interventions
Participants will be randomly allocated by sealed envelope to receive either:
1. During Foley balloon cervical ripening, the catheter will be tugged intermittently, every three hours to check for dislodgement (indicating a ripened cervix) following which the balloon will be retrieved and amniotomy and titrated oxytocin infusion can commence expediting labour and delivery
OR:
2. Standard care during Foley balloon cervical ripening whereby the Foley balloon will be passively left in place (no tugging) to await spontaneous expulsion. Following spontaneous expulsion with the cervix ripened, amniotomy and titrated oxytocin infusion can commence expediting labour and delivery

After 12 hours if the Foley has not been retrieved through tugging or spontaneously expelled, the balloon will be deflated and the catheter removed. The cervix will then be assessed to decide further management by the care provider guided by institutional care protocols and practices.

Standard care during labour induction, labour, delivery and after delivery will be provided to all participants

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Induction (Foley insertion) to delivery interval
2. Maternal satisfaction with birth experience after labor induction by 11-point 0-10 Visual Numerical Rating Scale.

Key secondary outcome(s))
Maternal outcomes
1. Change in bishop score after intervention (obtained from hospital record after hospital discharge)
2. Use of additional method for cervical ripening (obtained from hospital record after hospital discharge)
3. Time to delivery after Foley removal/expulsion (obtained from hospital record after hospital discharge)
4. Mode of delivery (obtained from hospital record after hospital discharge)
4.1. spontaneous vaginal
4.2. vacuum
4.3. forceps
4.4. caesarean section
5. Indication for operative delivery (obtained from hospital record after hospital discharge)
6. Duration of oxytocin infusion (obtained from hospital record after hospital discharge)
7. Blood loss during delivery (obtained from hospital record after hospital discharge)
8. Third-or fourth-degree tear (obtained from hospital record after hospital discharge)
9. Maternal infection (obtained from hospital record after hospital discharge)
10. Use of regional analgesia in labor (epidural) (obtained from hospital record after hospital discharge)
11. Length of hospital stay (obtained from hospital record after hospital discharge)
12. ICU admission (obtained from hospital record after hospital discharge)
13. Cardiorespiratory arrest (obtained from hospital record after hospital discharge)
14. Hysterectomy (obtained from hospital record after hospital discharge)
15. Maternal satisfaction with the allocated intervention

Neonatal outcomes (obtained from hospital record after hospital discharge)
16. Apgar score at 1 and 5 minutes (obtained from hospital record after hospital discharge)
17. NICU admission (obtained from hospital record after hospital discharge)
18. Cord artery pH (obtained from hospital record after hospital discharge)
19. Neonatal sepsis (obtained from hospital record after hospital discharge)
20. Birth weight (obtained from hospital record after hospital discharge)
21. Birth trauma (obtained from hospital record after hospital discharge)
22. Hypoxic ischaemic encephalopathy/need for therapeutic hypothermia (obtained from hospital record after hospital discharge)

Completion date
01/09/2024

Eligibility

Key inclusion criteria
1. One previous uncomplicated transverse lower segment cesarean section
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 classical caesarean section/hysterotomy/ 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 SARS-CoV-2 positive

Date of first enrolment
01/04/2023

Date of final enrolment
07/03/2024

Locations

Countries of recruitment

Malaysia

Study participating centre
University Malaya Medical Centre
University Malaya
Jalan Profesor Diraja Ungku Aziz
Lembah Pantai
Kuala Lumpur
Malaysia
59100

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 current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other unpublished results			17/09/2024	No	No
Participant information sheet	version 1 version 1	19/01/2023	28/03/2023	No	Yes

Protocol file	19/01/2023	28/03/2023	No	No