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Comparison of placement of the inflated transcervical Foley catheter for 6 or 12 hours in the labour induction of women with one previous Caesarean birth

Submission date
16/01/2022

Recruitment status
No longer recruiting

Registration date
19/01/2022

Overall study status
Completed

Last Edited
11/06/2025

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
Induction of labour (IOL) and Caesarean delivery are common obstetric procedures. Their occurrences are generally still increasing so it is increasingly common to have women with a previous Caesarean coming forward for IOL. IOL in women with a previous Caesarean is a higher risk procedure as there is a small risk of uterine rupture and a considerable risk of unsuccessful IOL requiring unplanned Caesarean delivery. However, in motivated and informed women delivering within a fully-resourced care setting, IOL after previous Caesarean is an acceptable practice as vaginal birth after Caesarean is associated with less morbidity (illness) for the mother and there is less risk of complications in future pregnancies.
Time to delivery is an important consideration during IOL because of its association with increased risk of Caesarean delivery, postpartum hemorrhage (bleeding after giving birth), and maternal and newborn infections. Moreover, a lengthy IOL process can burden busy delivery wards, increase healthcare costs and lower patient satisfaction.
A Foley catheter is a low-cost, long, flexible tube with a balloon at one end that can be inflated after insertion with sterile water. The Foley catheter is inserted through the neck of the womb (cervix) with the balloon then inflated just beyond to slowly dilate the cervix. A partially opened cervix then provides access to break the waters to help bring on labour pains. Studies have compared balloon placement for 6 compared to 12 hours with the use of a proprietary double-balloon catheter, finding that 6-hour placement hastens delivery. The aim of this study is to evaluate the placement of a low-cost single balloon Foley catheter for 6 vs 12 hours in women who have one previous caesarean section with closed cervixes undergoing IOL on the interval between catheter insertion to the birth of the baby.

Who can participate?
Women aged 18 years and over at term with one previous Caesarean and planned for IOL

What does the study involve?
The Foley catheter is typically inserted through the vagina into the lower womb. The balloon

near the tip of the catheter is then inflated with 80 ml of sterile water. After the balloon has been inflated and retained, the external tubing of the catheter will be taped to the inner thigh and the participant can move around freely and perform bodily functions without any impairment.
Once the catheter balloon has been placed, the fetal heart rate and contractions if any will be monitored for a short time to ensure the situation is reassuring. Then participants will be randomly assigned to one of the two interventions with an equal chance of being assigned to either group (i.e., removal of the catheter at 6 or 12 hours).

What are the possible benefit and risks of participating?
Different placement intervals before planned removal of the Foley catheter may or may not impact the interval to birth. Apart from the time to birth, the study is not anticipated to have an effect on other mother or baby outcomes. Major adverse outcomes arising from the interventions are not anticipated. Despite balloon ripening of the cervix, up to 90% of women induced with the Foley catheter require breaking of waters and a hormone drip to initiate contractions. Participants allocated to 6-hour placement may find that their cervix has not opened enough for their forewaters to be ruptured and further ripening is needed. If that is the case, options are available to continue the ripening.

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

When is the study starting and how long is it expected to run for?
September 2021 to February 2023

Who is funding the study?
University Malaya (Malaysia)

Who is the main contact?
1. Dr Usha Yogamoorthy
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Contact information

Type(s)
Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2021108-10681

Study information

Scientific Title
Foley catheter placement for labour induction in one previous Caesarean with unripe cervices for 6 compared to 12 hours: a randomised trial

Acronym
FOLIC

Study objectives
It is hypothesized that induction of labour with planned Foley catheter removed at 6 compared to 12 hours in women with one previous Caesarean delivery will result in a shorter time to birth.

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, +60 (0)379498473; ummc-mrec@ummc.edu.my), ref: MREC ID: 2021108-10681

Study design
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 additional files

Health condition(s) or problem(s) studied
Induction of labour

Interventions
Women with a history of one previous lower segment Caesarean section who are at term with unripe cervixes and have had Foley catheter placed trans-cervically and its balloon inflated for induction of labour will be randomised (using random.org application) to either catheter placement before planned removal at:
A) 6 hours or
B) 12 hours

Following Foley catheter placement to its planned removal, management is reactive. Vaginal examination and pulling on the Foley catheter to check dislodgement are avoided. If there are painful contractions, waters break, excessive vaginal bleeding, abnormal fetal heart rate tracing, fever, or concerning features, then vaginal examination followed by catheter removal, amniotomy, and oxytocin infusion may occur as appropriate within the 6- or 12-hour trial intervention periods in an appropriate response. In the event that the balloon is expelled spontaneously within the 6- or 12-hour trial intervention intervals, the usual actions to carry on with labour induction will be instituted.

Intervention Type
Procedure/Surgery

Primary outcome measure
Foley catheter insertion to birth interval (hours) measured using patient records

Secondary outcome measures
Maternal outcomes:
1. Estimate of the readiness of the cervix for labour measured using Bishop score calculated before insertion of the catheter and after removal of the catheter
2. Use of additional method for cervical ripening measured from patient records after removal of the catheter
3. Time to delivery after Foley removal measured from patient records between removal of the catheter and delivery
4. Mode of delivery measured from patient records at delivery
5. Indication for caesarean section measured from patient record at delivery
6. Duration of oxytocin infusion measured from patient records between delivery to discharge
7. Maternal satisfaction-based allocation to intervention until birth measured using 11-point Verbal Numerical Rating Score (VNRS) at delivery
8. Blood loss during delivery measured from patient records at delivery
9. Third -or fourth-degree tear measured from patient records at delivery
10. Maternal infection measured from patient records between admission and discharge
11. Use of regional analgesia in labour measured from patient records at delivery
12. Length of hospital stay measured from patient records between hospital admission and discharge

13. Need for ICU admission measured from patient records between hospital admission and discharge
14. Cardiorespiratory arrest measured from patient record between hospital admission and discharge
15. Need of hysterectomy measured from patient record between admission and discharge.
16. Uterine scar rupture / dehiscence measured from patient record between hospital admission and discharge

Neonatal outcomes:
1. Neonatal health measured using Apgar score at 1 and 5 min after delivery
2. Need for NICU admission measured from patient records between hospital admission and discharge
3. Cord pH measured at delivery
4. Neonatal sepsis measured from patient records between delivery and discharge
5. Birth weight measured from patient records at delivery
6. Birth trauma measured from patient records at delivery
7. Hypoxic ischemic encephalopathy/need for therapeutic hypothermia measured from patient records between delivery to discharge

Overall study start date
15/09/2021

Completion date
24/02/2023

Eligibility

Key inclusion criteria
1. One previous transverse lower segment Caesarean delivery
2. Bishop score ≤ 5
3. Age ≥18 years
4. Term pregnancy >36 weeks gestation
5. Singleton pregnancy
6. Cephalic presentation
7. Intact membrane
8. Reassuring fetal heart rate tracing
9. Absence of significant contraction ≥2 in 10 minutes
10. Successful Foley catheter insertion

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
126

Total final enrolment
126

Key exclusion criteria
1. History of hysterotomy/uterine perforation/myomectomy
2. Preference for repeat caesarean section
3. Latex allergy
4. Estimated fetal weight <2 kg or >4 kg
5. Placenta previa including minor previa
6. Major fetal malformations
7. Contraindication for vaginal delivery
8. Patient who is suspected COVID-19 infection or SARS-CoV-2 positive
9. Inability to given consent

Date of first enrolment
25/01/2022

Date of final enrolment
10/02/2023

Locations

Countries of recruitment
Malaysia

Study participating centre
University Malaya Medical Centre
Lembah Pantai
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Sponsor information

Organisation
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Sponsor type
Hospital/treatment centre

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ROR
https://ror.org/00vkrxq08

Funder(s)

Funder type
University/education

Funder Name
Universiti Malaya

Alternative Name(s)
University of Malaya, University Malaya, Malayan University, UM

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Malaysia

Results and Publications

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

Intention to publish date
24/02/2024

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 Dr Usha Yogamoorthy (y.usha@ummc.edu.my) subject to institutional review board approval.

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	07/10/2021	18/01/2022	No	Yes
Protocol file	version 1	07/10/2021	18/01/2022	No	No
Results article		19/09/2023	11/06/2025	Yes	No