UNIVERSITY OF MALAYA MEDICAL CENTRE

PARTICIPANT INFORMATION SHEET

Study Title:
Tugging the foley catheter every three hours in the labor induction of women with previous cesarean section : A randomized trial

Version No.: 1

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We would like to invite you to take part in a research study. Before you decide whether to participate, you need to understand why the research is being done and what it would involve. Please take time to read the following information carefully; talk to others about the study if you wish.

Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether you wish to take part.

INTRODUCTION

Induction of labour (IOL) occurs in 20–25% of births due to a variety of different reasons. Induction of labour (IOL) after one previous cesarean is a high risk procedure due to risk of failed induction and the small risk of uterine scar rupture. However in a well-motivated women it is an accepted practice and considered safe when conducted in a well-resourced setting as vaginal birth after Cesarean (VBAC) is associated with decrease maternal morbidity and a decreased risk of complication in future pregnancies.

The Foley catheter balloon (inflated to 60 ml) is commonly used to help open (ripen) the closed cervix (neck of the womb) as the initial 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 forewaters can then be broken and the oxytocin drip started to start contractions (labour pain) leading to labour and birth.

The usual practice is to leave the Foley balloon in place for 12 hours after insertion before removing it to check if the cervix has opened enough to let the balloon through into the upper vagina. In most women, the balloon can pass through the sufficiently opened cervix after only a few hours but retained in the vagina without causing discomfort. This scenario can delay the breaking of forewaters and of starting the oxytocin drip and probably of the birth.

We think that tugging on the catheter once every 3 hours after its insertion to check if the balloon has already passed the opened cervix and just sitting

comfortably in the vagina will allow much earlier discovery that the cervix is sufficiently open, ready for the forewaters to be broken, oxytocin started and birth expedited compared to the standard practice of waiting up to 12 hours before removing the catheter and checking if the cervix has opened.

1. What is the purpose of this study?

We plan to compare 3 hourly tugging vs standard management (no tugging) of Foley catheter in the labour induction of women with previous cesarean section to evaluate their impact on the time interval from start of induction to delivery.

2. Why is this study important?

Research has shown that mother's satisfaction with their labour induction is higher if the process takes a shorter time.

3. What type of study is this?

This is a randomized clinical trial. Neither you nor the researcher can choose the labour induction regimen. The allocation process is random (only revealed after opening of the allocated envelope after you have consented to participate and the Foley catheter has been inserted).

4. What is the procedure that is being tested?

The regime of care during IOL of 3 hourly tugging compared to standard management (no tugging) of the Foley's catheter.

5. Does the investigatory product contain culturally sensitive ingredients e.g., bovine, or porcine?

No

6. Why have I been invited to participate in this study?

You fulfill the inclusion criteria of this study.

- Scheduled labour induction
- One previous uncomplicated lower segment caesarean section
- Singleton fetus
- Term: ≥ 37 weeks gestation
- 18 years and above
- Cephalic presentation
- Reassuring fetal heart rate tracing
- Unripe cervix (Modified Bishop Score ≤ 5)
- Absence of significant contraction (≥ 2 in 10 minutes)
- Intact membranes
- Successful Foley insertion for IOL

7. Who should not participate in the study?

If you have these issues

- History of classical cesarean section/ hysterotomy/ uterine perforation/ previous myomectomy
- Latex Allergy

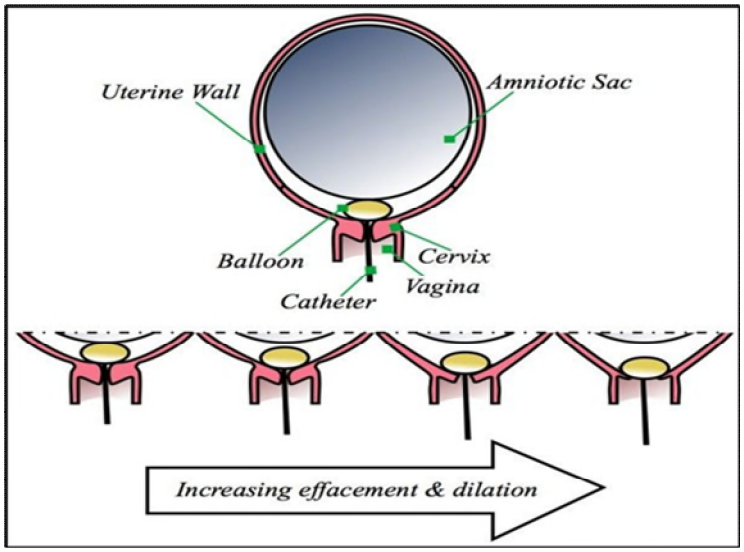
- Inability to given consent
- Known major fetal malformations/anomaly
- Contraindication for vaginal birth (e.g., placenta previa including minor)
- Patient who is suspected COVID 19 infection or COVID 19 positive
- Fetal weight clinically estimated to be ≤ 2 kg or ≥ 4kg before induction and confirmed by ultrasound

8. Can I refuse to take part in the study?

Yes. If you decline to take part, your care will not be affected, and you will be offered standard care

9. What will happen to me if I take part?

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 60 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 to either;

1) Tugging of the Foley catheter every 3 hours or
2) Standard management (no tugging) during the 12 hours placement

10. How long will I be involved in this study?

Your expected total duration of study participation will be from insertion of the Foley catheter for IOL to your discharge from hospital. However, the actual intervention time (3 hourly tugging) is 12 hours (or shorter if the balloon was spontaneously expelled as the cervix has dilated before

the scheduled time of removal) depending on the placement duration randomly allocated. Standard care for IOL, labour and delivery will equally apply to all participants after the 12-hour placement period.

11. What are the possible disadvantages and risks?

Major complications due to the interventions are not anticipated. Women with one previous Caesarean undergoing IOL are at high risk of needing another Caesarean and despite balloon ripening, most will require breaking of waters and a hormone drip to initiate contractions and start labour.

The Foley catheter tugging may be uncomfortable or even painful (tugging will cease on participant's 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 method for ripening are available from your care provider.

12. What are the possible benefits to me?

Three hourly tugging of the Foley's catheter may shorten the interval to birth and improve maternal satisfaction with their labour induction. The study is not anticipated to materially impact on other mother or baby outcomes.

13. Who will have access to my medical records and research data?

Only the investigators. Anonymized (where individuals cannot be identified) trial data may be released to other researchers in the future as permitted by the Ethics committee.

14. Will my records/data be kept confidential?

Yes. Appropriate security will be in place.

15. What will happen to any samples I give? (If applicable)

Not applicable

16. What will happen if I don't want to carry on with the study?

You can withdraw from the study at any time without having to provide any reason and your care will also not be affected in any way. Standard care will be provided.

17. What if relevant new information about the procedure/ drug/ intervention becomes available? (If applicable)

Not applicable.

18. What happens when the research study stops? (If applicable)

You will be offered standard care.

19. What will happen to the results of the research study?

The study findings will be published to help guide IOL care on a global basis.

20. Will I receive compensation for participating in this study?

No payment or compensation will be given.

21. Who funds this study?

Department of Obstetrics and Gynaecology, PPUM.

22. Who should I contact if I have additional questions/problems during the course of the study?

Name of investigator 1: Dr. Yunesh Krishnan
Affiliation Medical Officer Obstetrics and Gynaecology
Telephone number 011 33275017

Name of investigator 2: Prof Tan Peng Chiong
Affiliation Consultant in Obstetrics and Gynaecology
Telephone number 03 79492049

Name of investigator 3: Associate Prof Dr Aizura Syafinaz Ahmad Adlan
Affiliation Consultant in Obstetrics and Gynaecology
Telephone number 012 3375808

23. Who should I contact if I am unhappy with how the study is being conducted?

Medical Research Ethics Committee
University of Malaya Medical Centre
Telephone number: 03-7949 3209/2251