UNIVERSITY OF MALAYA MEDICAL CENTRE

# PARTICIPANT INFORMATION SHEET

**Study Title: 6 Hours vs 12 Hours of Foley Catheter Placement for Labour Induction in Nulliparas with Unripe Cervices: A Randomised Trial**
**Version No: 1.0**

**Version Date: 2/10/2021**

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 or not you wish to take part.

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## INTRODUCTION

Approximately 20–25% of pregnant women undergo labour induction (IOL) for a variety of reasons with many requiring cervical ripening because the cervix is still closed. IOL has merit when the benefits of delivery outweigh the risks of continuing the pregnancy to natural onset of labour.

Time to delivery from the start of IOL is an important consideration because the longer that takes, usually the risk of caesarean delivery, heavy vaginal bleeding after birth, infections in both mother and baby are higher and mothers' satisfaction with IOL is reduced.

In 2020 and 2021, two studies comparing placement for 6 vs 12 hours with the double-balloon catheter was published, showing a faster time to delivery with 6-hour placement. In PPUM the single-balloon Foley catheter is used for cervical ripening and it can be left in place for up to 24 hours. There is currently no data on whether the effect will be the same with the Foley catheter with 6-hour placement.

1. **What is the purpose of this study?**
   We plan to compare removal of Foley catheter after 6 vs 12 hours placement in women delivering their first child to evaluate their effect on time to delivery.

2. **Why is this study important?**
   This study is important as an IOL method that can speed up time to delivery can have advantages. There is no current data to guide practice with the commonly used single-balloon Foley catheter for 6 compared to 12 hours placement.

**3. What type of study is this?**

This a randomised 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?**

6 vs 12 hours placement of Foley catheter before removal for IOL in women with unripe cervices delivering their first child

**5. Does the investigatory product contain cultural sensitive ingredients eg: bovine or porcine?**

No

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

You fulfil the inclusion criteria of this study.

- Scheduled labour induction
- Nulliparous (no previous pregnancy beyond 20 weeks)
- 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
- Bishop score ≤ 5

**7. Who should not participate in the study?**

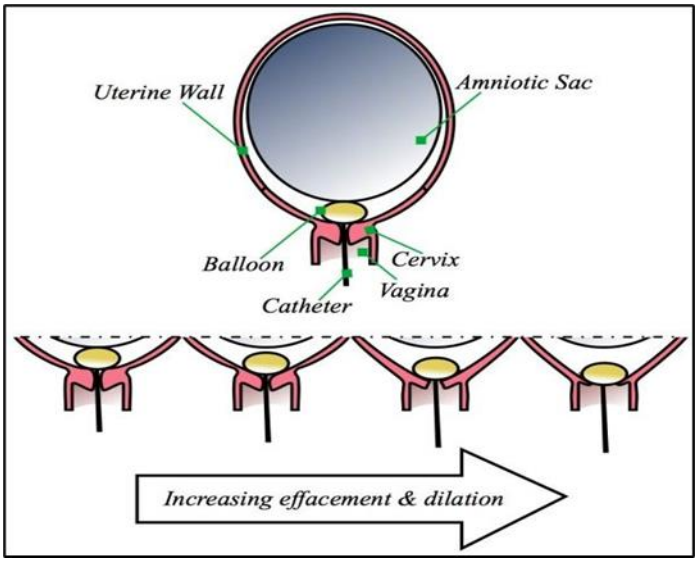
- Previous uterine incision/ injury (caesarean delivery, surgical removal of fibroid, uterine perforation)
- Baby has severe structural abnormality
- Contraindication for vaginal birth
- Fetal weight clinically estimated to be ≤ 2 kg or ≥ 4kg before induction and confirmed by ultrasound

**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 80 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

Removal of the Foley after
a) 6 or
b) 12 hours of 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 is 6 or 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 6- or 12-hour placement period.

**11. What are the possible disadvantages and risks?**

Major complications are not anticipated. Induction in women delivering their first usually child takes longer and despite balloon ripening, almost all will require breaking of waters and a hormone drip to initiate contractions and

start labour.

Participants allocated to 6-hour removal may find that their cervix might not have ripened sufficiently to allow their waters to be broken and further ripening needed. There are various options available in this situation.

**12. What are the possible benefits to me?**
6-hour placement before removal of the Foley may shorten the interval to birth. Apart from the time to birth, 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. Anonymised (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. Umadevi Appadurai
Affiliation Medical Officer Obstetrics and Gynaecology
Telephone number 0163805247

Name of investigator 2 Prof Tan Peng Chiong
Affiliation Consultant in Obstetrics and Gynaecology
Telephone number 0379492049

**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