UNIVERSITY OF MALAYA MEDICAL CENTRE

PARTICIPANT INFORMATION SHEET

Version 1 **Date:**
17/07/2018

FOLEY CATHETER VERSUS FOLEY CATHETER AND CONTROLLED-RELEASE DINOPROSTONE INSERT LABOUR INDUCTION OF NULLIPAROUS: A RANDOMISED TRIAL

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. 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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1. What is the purpose of this study?

Induction of labour in a woman having her first baby with an unripe cervix remains a challenge because it often takes more than 24 hours to achieve delivery and in 24-42%, induction is unsuccessful and Caesarean delivery is needed.

Prostaglandin vagina preparations and the Foley catheter are currently in first line use for induction of labour in UMMC when the cervix is unripe. They are considered to be of about equivalent effectiveness.

Prostaglandin softens the cervix but can trigger contractions at the same time. Controlled-release Dinoprostone insert is a newer preparation of prostaglandin where the drug is gradually released for up to 24 hours so it is inserted only once compared to tablet and gel which are administered every 6 hours. The insert has the additional advantage over tablet and gel preparations as it can be immediately removed if contractions are too intense which may cause fetal distress.

The Foley catheter balloon open the cervix from internally by exerting steady pressure typically without contractions so breaking the waters and an oxytocin drip are more often needed to achieve delivery compared to prostaglandin induction. However, the Foley catheter can be more comfortable during ripening as painful contractions is minimised and potentially safer as intense contractions can cause fetal distress. The Foley catheter once inserted is usually left for 24 hours to effect cervical ripening.

Combining Foley catheter with prostaglandin at the same time for labour induction can speed up the delivery process but is not commonly done as there are relatively few studies on a concurrent approach. Previous concurrent use studies have used prostaglandin vaginal tablet or gel preparations where multiple vaginal applications are needed which is inconvenient and less satisfactory from the woman's perspective.

We think combining Foley catheter and controlled-release Dinoprostone when both devices are

inserted at the same setting and left for up to 24 hours to ripen the cervix and induce labour can have advantage over the current standard practice single device like the Foley catheter.

2. **What type of study is this?**
   This is a randomized controlled trial which means neither primary investigator nor participant knows beforehand which intervention will be allocated to you.

3. **Does the investigatory product contain cultural sensitive ingredients eg: bovine or porcine? (if applicable)**
   No

4. **Why have I been invited to participate in this study?**
   You are approached to participate as you are scheduled to have your labour induced.

5. **Who should or should not participate in the study?**

To participate, you must be/ have :	You must not participate in the study, if you have :
-Women having her first baby -Unfavourable cervix (Bishop score <6) -Aged 18 years and above -≥37 weeks of gestation at enrolment -Singleton -cephalic presentation -Membrane intact -Normal pre-induction CTG (cardiotocography)	-Gross Fetal anomaly -Any allergy to latex or Dinoprostone

6. **Can I refuse to take part in the study?**
   Yes. Your care will not be affected.

7. **What will happen to me if I take part?**

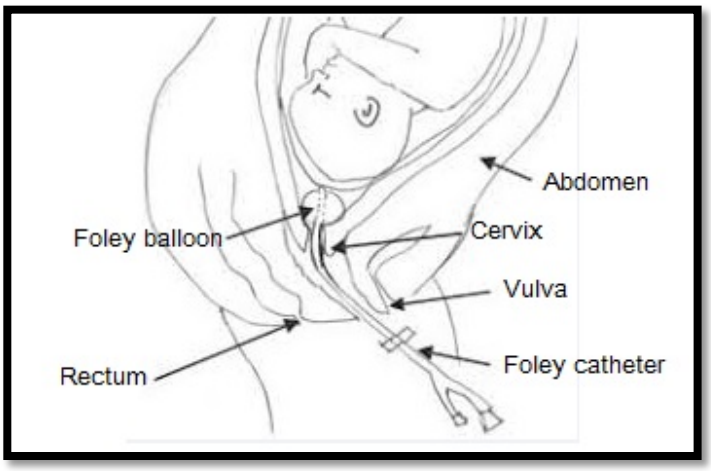
   All participants will have Foley catheter inserted in the usual fashion with the use of speculum into the uterus through the cervix and the balloon inflated with 60 ml of sterile water. This insertion usually takes a few minutes requiring you to be positioned on your back in a bed. Participants who are randomised to Foley catheter plus controlled release Dinoprostone insert will then have the insert placed in the upper vagina which should take seconds only.

   The Foley catheter tubing will be tapped onto the thigh with minimal tension. The controlled release dinoprostone insert is designed with a retrievable “string” just beyond the vaginal opening.

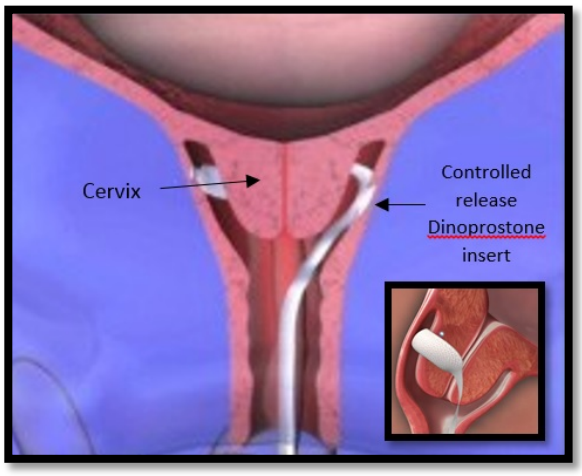
   You will be monitored regularly including with an electronic fetal heart rate monitor (CTG) at least every 6 hours. The Foley catheter and controlled release Dinoprostone insert will be removed after 24 hours unless already spontaneously expelled or removed earlier for standard medical reasons.

   After device removal at 24 hours, you receive standard PPUM labour care as decided with your care provider in accordance with your wishes. If the cervix is still unripe and your baby and you are in good condition, further attempt at ripening is reasonable.

At 6 hours after device placement and after delivery, we would like you answer a short questionnaire aimed at establishing your satisfaction with the labour induction and birth process.



Foley catheter position



Controlled release Dinoprostone insert position

8. **How long will I be involved in this study?**
   You will involve with this study from the initiation of labour induction until your delivery.

9. **What are the possible disadvantages and risks?**
   It is not known which method have better outcome. If you are randomised to the inferior method, then the time taken to delivery can be longer and you may be less satisfied. We are not anticipating a difference in Caesarean delivery rate.

10. **What are the possible benefits to me?**
    It is not known which method have better outcome or outcome maybe similar. If you are randomised to the superior method, then the time taken to delivery can be shorter and you may be more satisfied.

11. **Who will have access to my medical records and research data?**
    Investigators.

12. **Will my records/data be kept confidential?**
    Yes.

13. **What will happen if I don't want to carry on with the study?**
    You can withdraw at any time without giving any reason and your subsequent care will not be affected.

14. **What happens when the research study stops? (if applicable)**
    You will continue to receive standard UMMC care for your induction of labour and delivery.

15. **What will happen to the results of the research study?**
    We intend to publish the study findings

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

No

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

Name of investigator 1: Dr. Naumi Binti Laboh
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Name of investigator 2: Professor Dr. Tan Peng Chiong
Affiliation: University of Malaya Medical Centre
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Name of investigator 3: Associate Professor Dr. Vallikkannu Narayanan
Affiliation: University of Malaya Medical Centre
Telephone number (Mobile number): 0123040642

18. 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