UNIVERSITY OF MALAYA MEDICAL CENTRE

PARTICIPANT INFORMATION SHEET

Version 1 **28/09/2018**

Research title : Outpatient vs inpatient Foley catheter induction of labour in multiparous women: 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?

Conventionally induction of labour takes place in hospital setting as induction process was thought to be painful and associated with serious complications; uterine hyperstimulation, uterine rupture and abnormal fetal heart rate pattern which normally associated with pharmacological method of induction.

Foley catheter fit into picture as the ideal method of cervical ripening for outpatient basis, as it rarely causes uterine contraction, pain/discomfort, vaginal bleeding, non-reassuring fetal heart rate, uterine tachysystole, uterine rupture and intrauterine infection. Foley catheter can separate induction process into discrete steps where it ripens the cervix and rarely causes progression to spontaneous labour without amniotomy and oxytocin augmentation. This allows the induction process to be more controlled. Hence it is practical for foley catheter to be used as outpatient basis.

Moving cervical ripening from inpatient to outpatient setting may reduce the duration of hospital stay, allowing mother to sleep at home without worrying of going into labour. This may increase maternal satisfaction while balancing the safety to both mother and baby.

Study by Levine et al, showed the mean duration from induction to delivery interval for multiparous women with foley catheter is about 14.8hours (±5.6hours). The best time for delivery would be during the “working hours” which is from 8am to 6pm, where most of the health care resources will be optimal. Hence, we proposed for cervical ripening process to be done in the evening around 8pm.

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 :
-multiparous -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 are required to come to labor room in the evening for pre-induction CTG and bishop score assessment. If the CTG and Bishop Score are not suitable, participants will be excluded from the study. Those with favourable Bishop score will be asked to come back the following day for artificial rupture of membrane and Pitocin commencement.

   All participants will have Foley catheter inserted in the usual fashion with the use of speculum/digitally 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. The Foley catheter tubing will be taped onto your thigh with minimal tension. Fetal monitoring will be performed immediately after inflation of the foley catheter.

   Participants will then be randomized into 2 groups: outpatient or inpatient. Those randomized into outpatient group will be allowed to go back and to come back the next day morning after 12hours. When discharged, you will be given a written document which listed the conditions that you should be aware of and seek immediate medical attention if it were to occur, such as:
   -leaking of amniotic fluid
   -per vaginal bleeding

-pain or severe discomfort
-decreased fetal movements
-painful contractility (>2contractions/10 min)
-fever (T > 38^0C)

Patients in inpatient group were monitored and oriented in accordance to the Department's protocol.

After Foleys removal at 12 hours or earlier, you will receive standard PPUM labour care. If the cervix is still unfavourable and you and your baby are in good condition, further attempt at ripening is reasonable.

After delivery, we would like you to answer a short questionnaire aimed at establishing your satisfaction with the labour induction and birth process.

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?**
   The risks associated with outpatient foley induction of labor are minimal.

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, you may be more satisfied and the time spend in the hospital may be less.

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. Tan Yi Pin
Affiliation: University of Malaya Medical Centre
Telephone number (Mobile number): 0175398075

Name of investigator 2: Professor Dr. Tan Peng Chiong
Affiliation: University of Malaya Medical Centre
Telephone number (Mobile number): 0123052970

Name of investigator 3: Professor Dr. Siti Zawiah Omar
Affiliation: University of Malaya Medical Centre
Telephone number (Mobile number): 0192428810

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

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OUTPATIENT INFORMATION SHEET

Version 1 **28/09/2018**

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1) **Average time for catheter to dislodge is about 6.9 ± 3.9 hours. We expect about 80% of you will have balloon catheter dislodged when you are at home.**

2) **What do you need to do if the balloon catheter dislodged when you are at home?**
If you do not feel strong contraction pain and there is no leaking liquor, you can keep the dislodged balloon catheter in a plastic bag and come to labour room the next morning for further assessment. You are required to record the time when this happen

3) **When do you need to seek medical attention as soon as possible?**
- leaking of amniotic fluid
- per vaginal bleeding
- pain or severe discomfort
- decreased fetal movements
- painful contractility (>2contractions/10 min)
- fever (T > 38^0C)

4) **Who should I contact if I have additional questions/problems when I am at home?**

Name of investigator 1: Dr. Tan Yi Pin
Affiliation: University of Malaya Medical Centre
Telephone number (Mobile number): 0175398075