UNIVERSITY OF MALAYA MEDICAL CENTRE

PARTICIPANT INFORMATION SHEET

Study Title: FOUR HOURS VERSUS EIGHT HOURS VAGINAL EXAMINATION INTERVAL AFTER AMNIOTOMY LABOUR INDUCTION

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 or not you wish to take part.

Attention to the investigator: Please fill in simple layman language as you would speak to research subjects.

1. **What is the purpose of this study?**
   We plan to compare maternal satisfaction and duration of labour among multiparous women after foley's induction of labour when vaginal examination is done every 4 or 8 hours in active labour.

2. **Why is this study important?**
   This study is important as to our best knowledge data on clinical trial is lacking in context of vaginal examination interval on maternal satisfaction and duration of labour. Furthermore, it may be a benchmark to change of standard practice.

3. **What type of study is this?**
   Randomized controlled trial. Neither you nor the researcher can choose which group of vaginal examination interval you will be allocated to. The allocation process is random (only revealed after opening of the allocated envelope after you consented to participate and found to be eligible)

4. **What is the procedure that is being tested? (If applicable)**
   Vaginal examination in every 4 hours or 8 hours interval during labour.

5. Does the investigatory product contain cultural sensitive ingredients eg: bovine or porcine? (if applicable)

Non applicable

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

You have been invited to participate in this study because you are planned for induction of labour and fulfilled criteria as below:

a. Multiparous
b. Age 18 years and above
c. Gestational age of ≥ 37weeks at enrolment scheduled for induction of labour (Gestational age estimations were all supported by ultrasonographic dating)
d. Scheduled induction of labour
e. Viable pregnancy
f. Cephalic presentation
g. Singleton pregnancy
h. Women who had cervical ripening with Foley catheter only and favourable cervix with cervical dilatation of 3cm or greater (suitable for amniotomy) with contraction < 1:5min
i. Reassuring pre induction fetal cardiotocography (CTG)
j. Intact membrane
k. Woman with no previous uterine surgery

7. Who should not participate in the study?

Women with any one of below criteria:

a. Previous uterine scar (caesarean/myomectomy)
b. Women with ruptured membranes
c. Contraindication to vaginal delivery
d. Known gross fetal anomaly
e. Fetal weight clinically estimated to be ≤ 2 kg & ≥ 4kg and confirmed by ultrasound

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

Yes, and you will be treated similarly as others with similar condition not participating in this study.

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

You will be randomly assigned to one of the groups below. You have an equal chance of being assigned to either group.

Group 1: Four hourly vaginal examination interval after artificial rupture of membrane performed, or ealier if clinically indicated/warranted

Group 2: Eight hourly vaginal examination interval after artificial rupture of membrane performed, or earlier if clinically warranted

10. How long will I be involved in this study?
Your expected duration of study participation will be from post amniotomy labour induction to delivery of your baby.

11. What are the possible disadvantages and risks?
Artificial rupture of membrane can cause some pain and discomfort. Oxytocin can cause changes in fetal heart monitoring. Major complications are not anticipated. Artificial rupture of membrane and oxytocin is routinely performed as standard Labour room protocol of induction in women who has not given birth to augment the labour process.

12. What are the possible benefits to me?
It may reduce the number of vaginal examination performed, improve your satisfaction on birth process. Information obtained from this study will help to improve the management of labour in the future.

13. Who will have access to my medical records and research data?
Only the investigators and selected trained personnel will have access to your data.

14. Will my records/data be kept confidential?
Yes. All participants' anonymity is maintained. The participants will be given a unique Study ID upon recruitment into this study. This study ID will be the only mean of identifying the participants on the Case Report Form (CRF) and electronic database.

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

16. What will happen if I don't want to carry on with the study?
Each participant has the right to withdraw from the study at any time by informing the investigators. Upon withdrawal/discontinuation from this study, participants will be treated as any other patients with similar presentations but not participating in this study.

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)
Not applicable

19. What will happen to the results of the research study?
The result of this study may be presented at medical conferences or published in medical journals. However, all date obtained will be reported with no reference to a specific individual. Hence, every participant's data will remain confidential.

20. Will I receive compensation for participating in this study?
No payment or compensation will be given.

21. Who funds this study?
Obstetrics and Gynaecology Department UMMC.

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

Name of investigator : Dr Aishah Binti Mohd
Affiliation : Medical Officer of Obstetric & Gynaecology Department, UMMC
Telephone number : 0167028475

Name of investigator : Dr Maherah Binti Kamarudin
Affiliation : Lecturer/Specialist of Obstetric & Gynaecology Department, UMMC
Telephone number : 0127440731

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