PARTICIPANT INFORMATION SHEET

Study Title: Vaginal examination at 8 hours compared to 4 hours after commencement of oxytocin augmentation in nulliparous women: A randomized controlled trial
Version Date: June 3, 2023

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.

INTRODUCTION

Recent studies have consistently shown that labour takes longer than previously thought. Labour also takes longer with the first baby. It is more common to detect delay in the progress of labour at a woman's first labour and birth. The oxytocin drip is used to optimise contractions and speed up labour after a delay in progress has been identified. The flow of the oxytocin drip is adjusted according to the frequency of the contractions. After the drip has started, the initial rate of cervical can still be slow until the cervix reaches 6 cm after which the speed of cervical opening tends to speed up.

Vaginal examination is used to assess the progress of labour. Vaginal examination does not affect the progress of labour (the rate of cervical opening). It is not needed to adjust of the oxytocin drip flow rate. Women who have given birth often say that vaginal examinations in labour are performed too often and the examination can cause distress.

The current recommendation is to do a vaginal examination every 4 hours. There is some concern that vaginal examination findings can sometimes lead to unnecessary interventions, such as caesarean section, as it may still be too soon to say that labour is not progressing only 4–6 hour interval after starting oxytocin. There is evidence that oxytocin can be given for at least 8 hours to maximise the chance of normal birth. There is also evidence that even when the labour lasts longer than 30 hours, the baby is not at risk.

We are performing a study whereby if your oxytocin drip for slow labour was started at the early part of labour when the cervix is only less than 6 cm dilated if current monitoring does not give rise to concern for you or your baby, we will compare doing the next "routine" vaginal examination at 8 hours compared to 4 hours. However, if there is any concern whatsoever, your doctor can do a vaginal examination at any time (e.g., there are signs that your baby's delivery is imminent or you want an epidural).

1. **What is the purpose of this study?**
   We plan to show that the number of vaginal examinations can be safely reduced without affecting the speed of labour as the findings from the first routine vaginal examination after starting the oxytocin drip does not help to adjust the oxytocin drip flow rate and a diagnosis that labour has stopped progressing should not be made at 4 hours (and caesarean section done –

there is no other option except wait) if the monitoring of the mother's condition including contractions and life signs and the continuous monitoring of baby's heart rate are reassuring.

2. Why is this study important?

This study can be important as it may reduce typically unwanted vaginal examinations in labour without any impact on the labour progress. Hasty diagnosis of labour dystocia (a labour that is no longer capable of progressing) can lead to unnecessary caesarean or to start pushing too quickly leading to maternal exhaustion and unnecessary vacuum or forceps delivery. Reducing unnecessary vaginal examination may also optimise care resources, allowing staff looking after you to focus on more important care tasks. There is also some evidence that frequent vaginal examinations in labour may increase risk of infection affecting the womb.

3. What type of study is this?

This a randomized clinical trial. Neither you nor the researcher can choose which vaginal examination regimen you will be allocated to. The allocation process is random (only revealed after opening of the allocated envelope after you consented to participate and is fully eligible).

4. What is the procedure that is being tested?

The first routine vaginal examination after starting oxytocin for slow labour progress will be planned for in 8 or 4 hours' time.

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

Not applicable

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

You fulfil the inclusion criteria of this study.

- Spontaneous labour
- Nulliparous (No prior pregnancy > 22 weeks)
- Singleton pregnancy
- Gestational age of ≥ 37 weeks
- 18 year old and above
- Cervical dilatation at < 6 cm
- Oxytocin augmentation for labour delay actioned and started

7. Who should not participate in the study?

- Abnormal fetal heart rate tracing
- Previous uterine trauma (myomectomy, perforation)
- Major fetal malformation
- Meconium staining of liquor
- Chorioamnionitis
- Severe preeclampsia
- Non-reassuring maternal status
- Contraindication for vaginal delivery

8. Can I refuse to take part in the study?
Yes. You care will not be affected. You will be given usual labour care.

9. What will happen to me if I take part?
Your next vaginal examination will be performed at 8 or 4 hours from your last examination unless there is a specific need as decided by your doctor to do one sooner. After that your care will be according to usual practice.

10. How long will I be involved in this study?
Your expected duration of study participation will be from recruitment up to your discharge from hospital.

11. What are the possible disadvantages and risks?
It is possible that with examination at 4 hours, the findings may contribute information that lead to management changes like stopping the oxytocin as you are making good progress though current evidence suggests this action may increase caesarean risk though it reduces the chance of too frequent contractions and changes to the baby's heartbeat. It is also possible that oxytocin drip flow rate may be increased by the doctor if progress is still slow at 4 hours, quickening the progress but there is currently no evidence to support this. The current recommendation is to adjust the oxytocin drip flow rate by monitoring contractions not from vaginal examination.

12. What are the possible benefits to me?
You maybe exposed to fewer vaginal examinations as during the 8 hours, you may already show obvious signs of delivery, avoiding an unnecessary interim routine vaginal examination. There may be a lower risk of caesarean delivery arising out of a too early diagnosis of labour arrest (as you will not be examined until at 8 hours). Risk of infection may be reduced with fewer vaginal examinations.

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.

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)

Not applicable

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

We intend to publish the study's findings in a scientific journal to inform care providers and women on this aspect of labour care.

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, UMMC.

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

Name of investigator 1 Dr. Li Kong Wei
Affiliation Medical Officer Obstetrics and Gynaecology
Telephone number: 011-10023963
Email: Likongw9@gmail.com

Name of investigator 2 Prof Tan Peng Chiong
Affiliation Consultant in Obstetrics and Gynaecology
Telephone number 03-7949 1059
Email: pctan@um.edu.my

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
Email: ummc-mrec@ummc.edu.my