UNIVERSITY OF MALAYA MEDICAL CENTRE

PARTICIPANT INFORMATION SHEET

Study Title: Sonographic cervical length and its impact on timing of delivery and inducibility of labour

Version No: 2

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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?

Electively inducing labour at 39 weeks on a planned date as opposed to 41 weeks gestation would be better in terms of patient satisfaction, the mother has control over her delivery date instead of having to anxiously wait for the labour to happen. This would give her more freedom to choose the delivery date and reduce the anxiety of waiting for the symptoms and signs of labour. We propose that patient satisfaction would be better in patients who have planned induction of labour.

2. Why is this study important?

To improve the knowledge on the cervical length at term. To learn more on induction of labour at 39 weeks in nulliparous women compared to expectant management. This could help the other patients in future.

3. What type of study is this?

Observational study with Randomised controlled trial on a subgroup of patients.

4. What is the procedure that is being tested? (If applicable)

The transvaginal scan will be done on all the patients at term. But in a subgroup of patients with favourable cervical length we are testing induction of labour at 39 weeks vs expectant management.

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

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

Because you fulfill the inclusion criteria for this study that is no previous deliveries, short cervical length less than 27mm on transvaginal scan and no other medical problems during pregnancy that requires early delivery.

7. **Who should not participate in the study?**
   Those who have previous deliveries, contraindication for vaginal delivery, previous uterine surgery and having medical problems in pregnancy

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

9. **What will happen to me if I take part?**
   We will do a vaginal scan to assess the cervical length and if favourable ie < 27mm, would be randomised into induction of labour or expectant management.

10. **How long will I be involved in this study?**
    One day

11. **What are the possible disadvantages and risks?**
    A vaginal scan would be done at term. Studies have shown that it is less painful when compared to a digital vaginal examination. Patients may have a subjective feeling of more pain when compared to normal labour when labour is being induced.

12. **What are the possible benefits to me?**
    You can have a planned early induction of labour. Studies show that induction of labour at 39 weeks gestation with favourable cervix could probably reduce caesarean section and reduce the stillbirth rate. By doing the vaginal scan, we are identifying the subgroup of patients who are easily inducible.

13. **Who will have access to my medical records and research data?**
    Only the principal investigator and the research assistant

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

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

16. **What will happen if I don't want to carry on with the study?**
    You can get excluded from the study at any time.

17. **What if relevant new information about the procedure/ drug/**

intervention becomes available? (If applicable)
Nil applicable

18. **What happens when the research study stops? (If applicable)**
Nil applicable

19. **What will happen to the results of the research study?**
We would like to publish in a reputed journal

20. **Will I receive compensation for participating in this study?**
Nil applicable

21. **Who funds this study?** Grant form UM/UMMC O&G dept

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

Name of investigator 1: Dr. Vallikkannu Narayanan
Affiliation University of Malaya
Telephone number (Mobile number)0123040642

Name of investigator 2 : Prof Tan Peng Chiong
Affiliation University of Malaya
Telephone number (Mobile number) 0123052970

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