PARTICIPANT INFORMATION SHEET

Study Title: Foley Catheter Compared with Dinoprostone Sustained Released Vaginal Insert for Labour Induction after One Previous Caesarean: A Randomized Controlled Trial

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.

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1. Introduction (Scientific basis of this study)

Induction of labour after one previous Caesarean is a high risk procedure because of concerns about scar rupture and the relatively high failure rate resulting in a repeat Caesarean. In selected cases after careful consideration and as requested by women, it is considered a safe process when conducted in a well-resourced setting such as at PPUM. Following a successful vaginal birth after Caesarean, maternal and fetal outcomes are usually excellent and future pregnancies are safer.

The longstanding standard method of induction of labour when the cervix is not favourable is with the use of prostaglandin in individual doses given into the vagina. Prostaglandin softens the cervix and can also cause contractions triggering off labour. Recently, a new preparation of prostaglandin with a vaginal insert containing a reservoir that slowly release the active drug. This type of drug delivery system is thought to have the advantage of a more gradual and safer release of prostaglandin compared to a tablet where absorption can be too rapid causing intense contractions. Also if intense contractions are produced, the insert can be easily removed.

The Foley catheter where balloon pressure on the internal opening of the cervix cause softening and opening (ripening) of the cervix usually without contractions. Breaking the waters and an oxytocin drip to produce contractions is more often needed in labour induction with the Foley catheter compared to when prostaglandins are used.

Both regimens are in current use at PPUM for labour induction of women with one previous Caesarean in PPUM.

At present, it is not known if the prostaglandin vaginal insert or the Foley balloon is more efficient when used to induce labour in women with one previous Caesarean and which method provide higher satisfaction to women.

2. What is the purpose of this study?

We plan to compare prostaglandin vaginal insert compared to Foley catheter in the induction of labour of women with one previous Caesarean in terms of the interval to achieving delivery and participant's satisfaction with the birth process following their labour induction

3. Why is this study important?

This study is important as to our best knowledge there is no information available (within a clinical trial context) on the relative performance of these two common labour induction methods in women with a previous Caesarean

4. What type of study is this?

This a randomized clinical trial. Neither you nor the researcher can choose which labour induction 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 found to be eligible).

What are the procedures to be carried out?

Women allocated to Foley will have a 16G catheter inserted digitally transcervically according to usual protocol and the balloon is to be inflated with 60 ml of water. If the digital insertion was unsuccessful, insertion using a speculum can be attempted. If either attempts were unsuccessful or Foley insertion is not tolerated (expected to happen in less than 3% of the time), cross-over to dinoprostone vaginal insert will be offered.

After insertion and balloon inflation, the catheter is to be strapped to the thigh with minimal traction. The catheter will be removed at 24 hours if not already expelled spontaneously, at membrane rupture, uterine hyperstimulation syndrome or if not tolerated (e.g. urinary retention).

Women allocated to dinoprostone sustained release vaginal insert will have their device inserted as per manufacturer's instructions and placed at the posterior fornix. The device will be removed at 24 hours if not already expelled spontaneously, at membrane rupture, uterine hyperstimulation syndrome or if not tolerated (e.g. urinary retention).

Immediately following insert or catheter placement, CTG will be performed for at least 30 minutes and stopped if reassuring. Subsequent CTG monitoring whilst the device is in situ will be a minimum of 6 hourly (long enough to obtain a reassuring recording). CTG can be performed at care provider discretion if there are interim events (e.g. regular strong contractions suggestive of labour).

Once the insert or catheter is removed and you are in labour, the care you will receive standard PPUM labour and delivery care.

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

No.

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

You fulfil the inclusion criteria of this study.

- Scheduled induction of labour (as decided with your care provider)
- One previous scar
- Aged 18 years and above
- Gestational age of ≥ 37 weeks at enrolment
- Unfavourable cervix (Bishop Score ≤ 5)
- Reassuring pre induction fetal cardiotocography (CTG)
- Cephalic presentation
- Singleton pregnancy
- Intact membranes

7. Who should not participate in the study?

- Allergic to latex
- Allergy or other specific contraindication to dinoprostone
- Inability to consent
- Known gross fetal anomaly
- Absolute contraindication to vaginal delivery
- Para ≥ 5
- Estimated fetal weight ≤2kg & ≥ 4kg

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

Yes. If you choose not to take part, your labour induction will proceed according to your care provider.

9. How long will I be involved in this study?

From the start of labour induction to delivery

10. What are the possible disadvantages and risks?

Induction of labour after one previous Caesarean is successful resulting in vaginal delivery is as few as 50% of cases. There is also a small risk of scar issues (up to 2-3%) which necessitates an urgent Caesarean delivery.

Our anticipation is that the above complications will occur in similar frequency with either of the induction method of this study.

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11. What are the possible benefits to me?

You should not expect any benefit as it is not known which of the study's labour induction method will be more efficient and will produce better satisfaction to the mother. The two methods may also be of equivalent performance.

12. Who will have access to my medical records and research data?

Only the investigators.

13. Will my records/data be kept confidential?

Yes.

14. 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 provided

15. Will I receive payment/ compensation for participating in this study?

No payment or compensation will be given.

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

Dr. Sivaranjani Sanmugam

University Malaya Medical Centre

Telephone number: 012-6025028

17. 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