UNIVERSITY OF MALAYA MEDICAL CENTRE

PARTICIPANT INFORMATION SHEET

Study Title: Self-Bladder Emptying Compared with Catheter Placement for Planned Caesarean Section: A Randomised Controlled Trial
Version No: 1
Version Date: 05/11/2021

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. What is the purpose of this study?

We plan to compare the performances between self-bladder emptying (peeing in the toilet) with bladder catheter placement at planned caesarean section to improve recovery and increase satisfaction.

2. Why is this study important?

A number of studies have provided information that self-bladder emptying (peeing in the toilet) from before Caesarean and through recovery reduces the risk of urine infection without causing any problem during surgery (no bladder injury observed) or urination difficulty in the immediate recovery period. However, one different type of study finds with catheter removed immediately after Caesarean completed, 13.6% have difficulty peeing and need the catheter to be put back for a short time. In a pre-study exercise amongst our UMMC patients, all 23 patients that we asked agree this study is important to help guide patient care but a few after their Caesarean have expressed concerns about their ability to get up to pee immediately after an operation while others find the catheter uncomfortable and would rather pee by themselves throughout. This study will add information particularly from the patients' perspective of satisfaction with these contrasting bladder managements for Caesarean.

3. What type of study is this?

Randomized controlled trial. Neither you nor the researcher can choose which bladder management you will be allocated to. The allocation process is random (only revealed after opening of an envelope after you consented to participate). You must be prepared to accept either method.

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

Self-bladder emptying compared with bladder catheter placement at planned caesarean section.

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

Not applicable

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

You are selected to participate in this research study because you are scheduled for a planned caesarean section in UMMC, aged 18 and above, carrying one baby at term (≥ 37 weeks) and the baby is considered healthy.

7. Who should not participate in the study?

You should not participate in this study if you:

- Have frequent urine infections during pregnancy or before
- Have a large (> 4 cm) ovarian or uterine mass
- Has pelvic adhesion or complication at previous surgery
- Difficult surgery or prolonged surgery time is expected e.g., placenta previa or accreta
- Have medical condition requiring monitoring of urine output after surgery

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

Yes, this study is entirely voluntary. If you decide not to participate, it will not affect your care.

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

You have an equal chance of being assigned to either group: A) Self-emptying of the bladder or B) Placement of bladder catheter.

If assigned to self-emptying of bladder you will be asked to pee in the ward just before being sent to the operating theatre. After the Caesarean, you are expected to go to toilet to pee normally, use a bedpan if needed or if unable to pee at all, have a catheter inserted. The catheter may be an in and out process or left in for a short time as decided by your doctor.

If assigned to catheter placement, a bladder catheter will be inserted on the operating table and left in until the next day to drain the bladder the whole time. After removal of catheter, you will be expected to pee in the toilet as normal. if unable to pee at all, another catheter will be inserted, as an in and out process or left in for a short time as decided by your doctor.

A bedside ultrasound bladder scan will be done to measure your bladder volume after peeing, a midstream urine sample collected before hospital discharge for urine infection testing, and questions on bladder function and recovery from caesarean will be asked. All other care aspects will be as standard.

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

Until discharged from the hospital. We will telephone about your urine result when available (about 7 days).

11. What are the possible disadvantages and risks?

Those allocated to self-emptying of bladder specific risks are

a) Operating field issue because bladder too filled up during surgery – catheter will be inserted after operation has begun
b) Injury to bladder – it will be repaired and catheter has to be left in for about 1-2 weeks
c) Unable to pee immediately after surgery – catheter in and out or left in for up to 24 hours

Those allocated to placement of catheter specific risks are

a) Urine infection
b) Slower overall recovery from Caesarean
c) After catheter removal, initial urination more uncomfortable and less satisfactory

12. What are the possible benefits to me?

There may or may not be any benefits to you; the purpose of the trial is to evaluate the trial interventions as there is uncertainty about which is better or they may be equivalent. Information obtained from this study will help guide the management of future patients in similar circumstances.

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

Only the investigators will have access to your medical records and research data. 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?

All your information obtained in this study will be kept and handled confidentially, following applicable laws and/or regulations. When publishing or presenting the study results, your identity will not be revealed without your expressed consent. Individuals involved in this study and your medical care, qualified monitors, auditors, the sponsor, its affiliates and governmental or regulatory authorities may inspect and copy your medical records, where appropriate and necessary. Data from the study will be archived for analysis, but your identity will not be revealed at any time.

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

Your urine sample will be sent to UMMC laboratory to look for infection, then discarded as per laboratory standard operating procedure.

16. What will happen if I don't want to carry on with the study?

You are allowed to withdraw at any point of the study without having to explain and withdrawal will not affect your care**.**

17. What if relevant new information about the procedure/ drug/ intervention becomes available? (If applicable)

You will be informed.

18. What happens when the research study stops? (If applicable)
If the study is stopped early for any reason, you will be informed. Your caesarean section and after care will be carried out as per usual practice.

19. What will happen to the results of the research study?
The trial findings are expected to be published in a medical journal to share knowledge and help guide practice globally.

20. Will I receive compensation for participating in this study?
No, there will not be any compensation provided and no additional expense.

21. Who funds this study?
Presently, the Department of Obstetrics & Gynecology, UMMC.

22. Who should I contact if I have additional questions/problems during the course of the study?
If you have any questions about the study, please contact the study doctor;

Dr Nabila Arfah Mohd Yassin, UMMC. H/P: 019 – 600-5886
Dr Maherah Kamarudin, UMMC. 03-79492059
Prof PC Tan, UMMC. 03-79492059

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