PARTICIPANT INFORMATION SHEET

**Study Title: Pipelle sampling with full bladder versus no intervention: a randomised clinical trial Version No: 1**

**Version Date: 17/03/2021**

*We want 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 its involvement. 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.*

1. **What is the purpose of this study?**

To show that full bladder improves failure rate of pipelle sampling at first attempt.

1. **Why is this study important?**

If performing pipelle sampling with full bladder is shown to reduce the failure rate, it can help to reduce the number of attempts, thus, reducing the discomfort during procedure.

1. **What type of study is this?**

This is a randomised-controlled trial

1. **What is the procedure that is being tested?**

Pipelle sampling.

1. **Does the investigatory product contain culturally sensitive ingredients, e.g., bovine or porcine?**

No applicable.

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

You have been invited to participate because you are required to have a pipelle sampling and fulfill other criteria to take part.

1. **Who should not participate in the study?**

You should not participate in the study if you have stenotic cervical os, ≤18 years, having infection over your cervix, intense anxiety, needed coincident endocervical curettage, needed general anaesthesia or local anaesthetics, used analgesic drugs before the pre-procedure, had a known history of malignancy, uterine lesions that distort the cervical canal or uterine cavity, had a history of fail pipelle sampling previously, or is currently pregnant.

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

Participation in this study is entirely voluntary. Not consenting to participate or withdrawal of consent will not affect your entitled medical services. You do not have to participate in this study to get treatment for your disease or condition. Declining to take part will not affect your care in any way.

1. **What will happen to me if I take part?**
2. You will be counselled regarding the procedure and sign an informed consent form.
3. You will get an ultrasound assessment to look into your pelvic organ.
4. You will be positioned on a bed, with your feet and legs propped up to allow vaginal examination.
5. Vaginal examination using speculum will be used to locate your cervix and os.
6. A pipelle will be introduced into your os to collect the endometrial tissue.
7. If pipelle is unable to be introduced, an instrument is placed on the cervix.
8. The endometrial biopsy catheter tip is inserted into the cervix, and a sample is collected.
9. All the instruments will be removed after the procedure.
10. If you are in the intervention group, you will be asked to drink 1 litre of fluid 1 hour before the procedure.
11. You will be asked to rate the overall pain score and overall satisfaction score.
12. **How long will I be involved in this study?**

Your participation in this research study will be once during the procedure only.

1. **What are the possible disadvantages and risks?**

Discomfort or cramping, infection, bleeding from cervix or near syncope due to pain.

1. **What are the possible benefits to me?**

To improve success rate/pain and discomfort during pipelle procedure.

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

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

1. **Will my records/data be kept confidential?**

All your information obtained in this study will be kept and handled confidentially according to 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 in 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.

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

It will be sent to the lab for the pathologist to interpret.

**What will happen if I do not want to carry on with the study?**

You may withdraw from the study at any stage without having to give a reason. Your care will not be affected if you choose to withdraw.

1. **What if relevant new information about the procedure/ drug/ intervention becomes available?**

You will be informed of any new information (relevant to the consent becomes available and may need to re-consent, based on new information.

1. **What happens when the research study stops?**

If the study is stopped early for any reason, you will be informed, and arrangements made for your care.

1. **What will happen to the results of the research study?**

It will be presented and published in the Clinical Masters final thesis and may be reproduced in international scientific journals.

1. **Will I receive compensation for participating in this study?**

No, there will not be any compensation provided.

1. **Who funds this study?**

The Department of Obstetrics & Gynaecology, UMMC.

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

If you have any questions about the study or if you may have a study-related injury and want information about treatment, please contact the study doctor;

Dr. Erwina Hashim,

Obstetrics and Gynaecology Department, UMMC

H/P: 0192010405

1. **Whom 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: 03-79493209/2251

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