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Effect of a full bladder in ensuring easier entry of a sampling device into the womb

Submission date 10/06/2021	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 17/06/2021	**Overall study status** Completed	
Last Edited 07/05/2024	**Condition category** Other	

Plain English summary of protocol

Background and study aims
Pipelle sampling is a procedure where a small amount of tissue is taken from the lining of the womb using a small straw-like device. The aim of this study is to show that a full bladder improves the failure rate of pipelle sampling at the first attempt.

Who can participate?
Women aged over 18 years with abnormal uterine bleeding undergoing pipelle sampling

What does the study involve?
Patients are allocated at random (by chance alone) to either perform the procedure directly with the doctor in charge, or be asked to drink a bottle of water and hold on to their urine until they have the urge to pass urine. Subsequently, an ultrasound will be performed over the abdomen. Next, the doctor will insert a device into the patient's vagina to see the cervix. A pipelle (a small straw-like device) will be passed through the cervix to get the tissue of the patient's womb's lining. After the sample is collected, all the instruments will be removed, and the procedure is considered done. Questionnaires are used to assess pain and satisfaction score after the procedure. Once the procedure is done, the patient will no longer be involved in this study.

What are the possible benefits and risks of participating?
If performing pipelle sampling with a full bladder is shown to reduce the failure rate, it may help to reduce the number of attempts and reduce the discomfort during the procedure.

Where is the study run from?
Pusat Perubatan Universiti Malaya (Malaysia)

When is the study starting and how long is it expected to run for?
March 2021 to June 2022

Who is funding the study?
Pusat Perubatan Universiti Malaya (Malaysia)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
MREC ID NO: 2021326-9984

Study information

Scientific Title
Pipelle sampling with full bladder versus no intervention: a randomised clinical trial

Acronym
PipFuB

Study objectives
Full bladder before pipelle sampling will reduce the failure rate during the first attempt of pipelle without cervical manipulation.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 10/06/2021, Medical Research Ethics Committee, University of Malaya Medical Centre (Jln Profesor Diraja Ungku Aziz, 59100 Kuala Lumpur, Malaysia; +60 (0)3 7949 3209/2251; iresearch@ummc.edu.my), ref: 2021326-9984

Study design
Single-blind single-centre prospective randomized controlled trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Endometrial sampling technique using pipelle sampler

Interventions
Patients who are indicated for pipelle sampling will be randomised to performing pipelle without intervention or pipelle with a full bladder.

Patients randomised to full bladder group will be given 1 l of water to drink and are asked to hold their bladder for 1 hour before proceeding to pipelle sampling.

Patient in the no intervention group may proceed to pipelle sampling directly.

Both groups will have an ultrasound performed to look at bladder volume and endometrial cavity length. During this assessment, they will be asked if they have the sensation to urinate. The doctor then will proceed with pipelle sampling using Pipelle® CCD manufactured by Laboratoire CCD – CE0459.

Randomisation to no intervention or full bladder was by opening a sealed opaque envelope.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Failure rate of performing pipelle sampling at first attempt without cervical manipulation (failure to perform a pipelle sampling is defined when the depth of the pipelle inserted is less than 4 cm) measured using patient records at the time of procedure

Key secondary outcome(s))
1. Pain assessed using an 11-point visual numerical rating scale score from 0-10 (high score, greater pain) during the procedure
2. Patient satisfaction assessed by asking 'Please rate the satisfaction with regards to the procedure you had' using an 11-point visual numerical rating scale score from 0-10 (high score, greater satisfaction) immediately after the procedure is completed
3. Analgesia use post-procedure measured by reviewing patient notes immediately after the procedure
4. Duration to complete procedure, defined as the time from speculum inserted into the vagina to speculum removed during the procedure

5. The bladder's volume measured using ultrasound performed 1 hour after drinking 1 litre of fluid or when the patient has the sensation to urinate
6. Sensation to urinate assessed by asking, 'Do you have the sensation to urinate now?' to bladder volume calculated by ultrasound during ultrasound assessment
7. The need for additional manoeuvres during the procedure (cervical manipulation) measured using patient notes
8. Failure rate after the manoeuvre, defined as when the depth of pipelle inserted is less than 4 cm, or when the patient requested for the procedure to be stopped measured using patient notes
9. Complications developed during the procedure, mainly cervical trauma or syncopal attack following a vaso-vagal attack measured using patient notes if analgesia use immediately after the procedure

Completion date
30/06/2022

Eligibility

Key inclusion criteria
1. All women with abnormal uterine bleeding indicated for pipelle sampling
2. Age ≥18 years old

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Total final enrolment
214

Key exclusion criteria
1. A known stenotic cervical os
2. Having acute cervicitis
3. Intense anxiety
4. Had been diagnosed with bladder dysfunction
5. Needed general anaesthesia or local anaesthetics
6. Used analgesic drugs before the pre-procedure
7. Known history of malignancy, uterine anomalies, or leiomyoma distorts the cervical canal or

uterine cavity
8. Had a history of failed office endometrial sampling procedure
9. Currently with a positive b-HCG test

Date of first enrolment
01/07/2021

Date of final enrolment
31/05/2022

Locations

Countries of recruitment
Malaysia

Study participating centre
Pusat Perubatan Universiti Malaya
Jln Profesor Diraja Ungku Aziz
Kuala Lumpur
Malaysia
59100

Sponsor information

Organisation
University Malaya Medical Centre

ROR
https://ror.org/00vkrxq08

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Malaya Medical Centre

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

IPD sharing plan summary

Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		06/05/2024	07/05/2024	Yes	No
Participant information sheet		17/03/2021	08/07/2021	No	Yes
Protocol file		17/03/2021	08/07/2021	No	No