

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	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 17/06/2021	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 07/05/2024	Condition category Other	<input type="checkbox"/> Individual participant data

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

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

See study outputs table

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 measure

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

Secondary outcome measures

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

Overall study start date

26/03/2021

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

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

214

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

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59100

Sponsor information

Organisation

University Malaya Medical Centre

Sponsor details

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Sponsor type

Hospital/treatment centre

Website

<http://www.ummc.edu.my/>

ROR

<https://ror.org/00vkrxq08>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

University Malaya Medical Centre

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

31/12/2022

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?
Participant information sheet		17/03/2021	08/07/2021	No	Yes
Protocol file		17/03/2021	08/07/2021	No	No

[Results article](#)

06/05/2024

07/05/2024

Yes

No