RESEARCH PROPOSAL FOR MASTER OF MEDICINE
(OBSTETRICS AND GYNAECOLOGY)
DEPARTMENT OF OBSTETRICS AND GYNAECOLOGY
UNIVERSITI MALAYA

TITLE

Micturition In The Toilet Environment Compared With The Bedpan In Nulliparous In Labour – A Randomized Control Trial

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TITLE:

Micturition in the toilet environment compared with the bedpan in nulliparous in labour – A Randomized Control Trial

INTRODUCTION AND LITERATURE REVIEW

Urinary retention is defined as a bladder volume significantly greater than the expected normal bladder capacity after voiding or an inability to completely empty the bladder (Yip SK 1998, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) 2014). Whereas post-void residual urine is defined as the volume of fluid remaining in the bladder immediately after the completion of micturition. Many authors, including the International Incontinence Society considers covert urinary retention when the patient is unable to pass more than 50% of normal bladder capacity or post-void residual volume is at least 150ml (Paola, 2014)8. Owing to the hormonal and mechanical effects of pregnancy, the abnormal amounts of residual urine for the parturients has yet to be defined. This can only be achieved with a large population of parturients and in view of its limited accuracy, to set 150ml as a cut-off value to consider as covert urinary retention is still the most suitable modality in this study. Thus, we can define satisfactory micturition as when there is without covert urinary retention (<150ml).

The elasticity of the urinary tract seems to be increased during pregnancy, partly due to hormonal effect causing reducing of the smooth muscle tone of the bladder. Thus, Muellner SR (1938) had proved that the capacity of the bladder increases during pregnancy. As pregnancy advanced, the muscles of the bladder lose tone and its capacity slowly increases. As a result, parturients would have the first desire to void when the bladder contains more than 250ml. B. Gyampoh (2004) had done a pilot study in applying a cut-off volume of 300ml, the volume at which a clinical decision regarding the need for emptying the bladder. It is not advisable to go beyond 400ml-500ml as in an intrapartum situation, smaller volumes may represent an obstruction to the descending head. Thus, by using 300ml of the bladder volume to consider the need for emptying the bladder in this study is a reasonable idea.

The National Institute for Health and Clinical Excellence, NICE guideline (2007) in Intrapartum Care 1.13.11: recommends urethral catheterization to empty the bladder and assist delivery when active maternal effort is ineffective during the second stage. While during the first stage of labour, urethral catheterization might not deem to be necessary by offering bedpan or mobilizing to the toilet. The length of established first stage of labour varies, average for first labours last about 8 hours and can be up to 18 hours; while women with second and subsequent labours last about 5 hours up to 12 hours. The ability to pass urine needs to be evaluated in view spontaneous voiding may become progressively difficult by the advancing fetal head. In this study, we will offer only to nulliparous (woman with first labours and no prior delivery beyond 20weeks of gestation) either by bedpan or mobilizing to toilet for their bladder needs with their recent vaginal dilatation between 4cm – 8cm. The recent vaginal examination should be within 2 hours. As long as there is no external sign of second stage (external genitals or anus begin to bulge out during contractions) and/or rectal pressure (have the urge to push/bear down), nulliparous is generally safe to mobilize. The duration to void in the toilet or in the bedpan will be set to be limited up to 10 minutes or until completion of micturition, whichever comes first. To consider as impaired micturition when they had covert urinary retention of at least 150ml by ultrasound scan measurement immediately post void.

From the previous practice, it was preferable to provide bedpan for the bladder needs in women in labour. Due to the advantages of mother friendly care, nowadays they should be encouraged to walk around and keep mobile rather than remaining in bed during labour. A randomized clinical trial was done by Anette B et al (2014) shows that the number of in-out catheterization is reduced significantly by mobilizing the postoperative patients which had underwent minor spine surgery in the recovery room to toilet instead of bedpan. Thus, it is believed that by offering the nulliparous in labour to mobilize to toilet for bladder needs instead of bedpan, they are more likely able to empty the bladder and also the number of in-out catheterization may be reduced.

On the other hand, from our current clinical practice, to determine the amount of residual urine and the need to empty the bladder is by palpating the bladder per abdomen, estimating the amount of fluid infused or the interval from last void. However all of which are imprecise measurement. B. Gyampoh et al. (2004) had carried out a prospective observational pilot study, he compared the urine volume that measured by real-time ultrasound scan with the volume that quantified by catheterization in the same women intrapartum, and the result showed ultrasonography estimation of bladder volume provides a good alternative in women in labour for the need of catheterization, with its sensitivity of 100% and specificity of 36%. It also has the advantage of being simple to use, safe, non-invasive, painless, reassuring to the expectant mother, repeatable and not associated with undesirable side effects. In another study, J.W.Barrington et al. concluded that bladder scan would be more accurate if women with ruptured membranes instead of intact membrane, in view difficult to differentiate the fetal urine (amniotic fluid) with maternal urine. Also, women with previous abdominal surgery might cause anatomy of the bladder to be distorted and the measurement with scan of residual urine would appear to be insufficiently accurate.

By offering mobilize to toilet, most likely can reduce the incidence of impaired micturition and subsequently can reduce the need for uretheral catheterisation. The procedure of urethral catheterisation not only can be unpleansant and embarrassing, but also it carries the risk of urethral trauma, urinary tract infection, and urethral stricture. Moreover, it can lead to negative psychological impact to the women. Bacteriuria introduced by repeated catheterisation can present the optimal condition for the development of urinary tract infection. Bladder catheterisation is also known to be a significant cause of morbidity to patients and a major cause of hospital-acquired infections. Michael Kaye (1962) had concluded that almost 3 fold increased in the number of bacterial counts in the urine (6% to 17%) found in those who had a single bladder catheterization intrapartum as compared to those who were not catheterized. Therefore, it recommends that this procedure should only be carried out where there is demonstrable evidence of benefit to the patient.

Hence, the design of this study is to see by offering mobilizing to toilet instead of bedpan, can improve the incidence of voiding difficulties intrapartum.

STUDY OBJECTIVE

To study whether the micturition is more satisfactory by mobilising to the toilet compared with bedpan for bladder needs in nulliparous in labour.

RESEARCH HYPOTHESIS

By offering mobilizing to toilet instead of bedpan can improve the micturition in nulliparous in labour.

ENDPOINT:

Primary outcome

- To study the satisfactory micturition by mobilising to the toilet compared with bedpan in nulliparous in labour

Secondary outcome

- Frequency of in-out catheterization during first stage of labour
- Duration of second stage
- Number of instrumental delivery
- Number of caesarean section
- Estimated blood loss during delivery
- Maternal satisfactory

METHODOLOGY

STUDY DESIGN

This is a prospective randomized-controlled, non-blinded study.

POPULATION OF STUDY

Nulliparous who admitted to labour and delivery suite in University Malaya Medical Centre, Kuala Lumpur

SAMPLING

Participant must fulfill the inclusion and exclusion criteria.

INCLUSION CRITERIA

- Aged 18 years and above
- Nulliparous (first labours and no prior delivery beyond 20weeks of gestation) in labour with recent cervical dilatation (within 2 hours) of 4cm – 8cm and without any external sign of second stage and rectal pressure
- Membrane ruptured
- Singleton live fetus
- Cephalic presentation
- Contraction pain of at least 3 in 10 minutes lasted for at least 15 sec
- Urge to micturate and/or palpable bladder
- Bladder volume of at least 300ml by ultrasound scan

EXCLUSION CRITERIA

- Any condition that is contraindicated for vagina delivery (e.g. Placenta previa major)
- Neurological disease involving bladder dysfunction
- Intact membrane as it can cause inaccuracy of the bladder scan
- Epidural analgesia in labour
- History of repeated (>2 during antenatal period) urinary tract infections
- Lower segment uterine fibroid
- No indication risk of immediate delivery (external sign of second stage and rectal pressure)

METHODS

Ultrasound Measurements:

The bladder volume is measured using an ultrasound machine, which employed a B-mode with a convex transducer at a frequency of 3.5 MHz. (B.Gyampoh, 2004)

Women will be in a semi-recumbent position during scanning.

Bladder measurements are performed in two planes (transverse and sagittal image), and will be done in between contractions, so as to avoid alteration of the bladder shape due to uterine contractions.

In the transverse image, the transducer is positioned horizontally along the long axis of the bladder, and move cranially, caudally and laterally until the maximum transverse section is found. The maximum transverse width is measured (horizontal diameter).

For the sagittal image, the transducer is then rotated through 90 degree into the sagittal plane, at the same point or with some alterations until the maximum sagittal section is obtained. The sagittal width and height are then measured.

Sagittal and transverse bladder measurements are recorded in order to determine the three radial measurements (height, depth and width of bladder, h, d and w), with a constant value of 1.74.

The formula of ultrasonography for urine volume estimation is:

V= 1.74 x h X d x w

(v: urine volume;

h: height, which is the sagittal width;

d: depth, which is the sagittal height; and

w: width, which is the transverse width)

It will be measured initially and repeated after voiding.

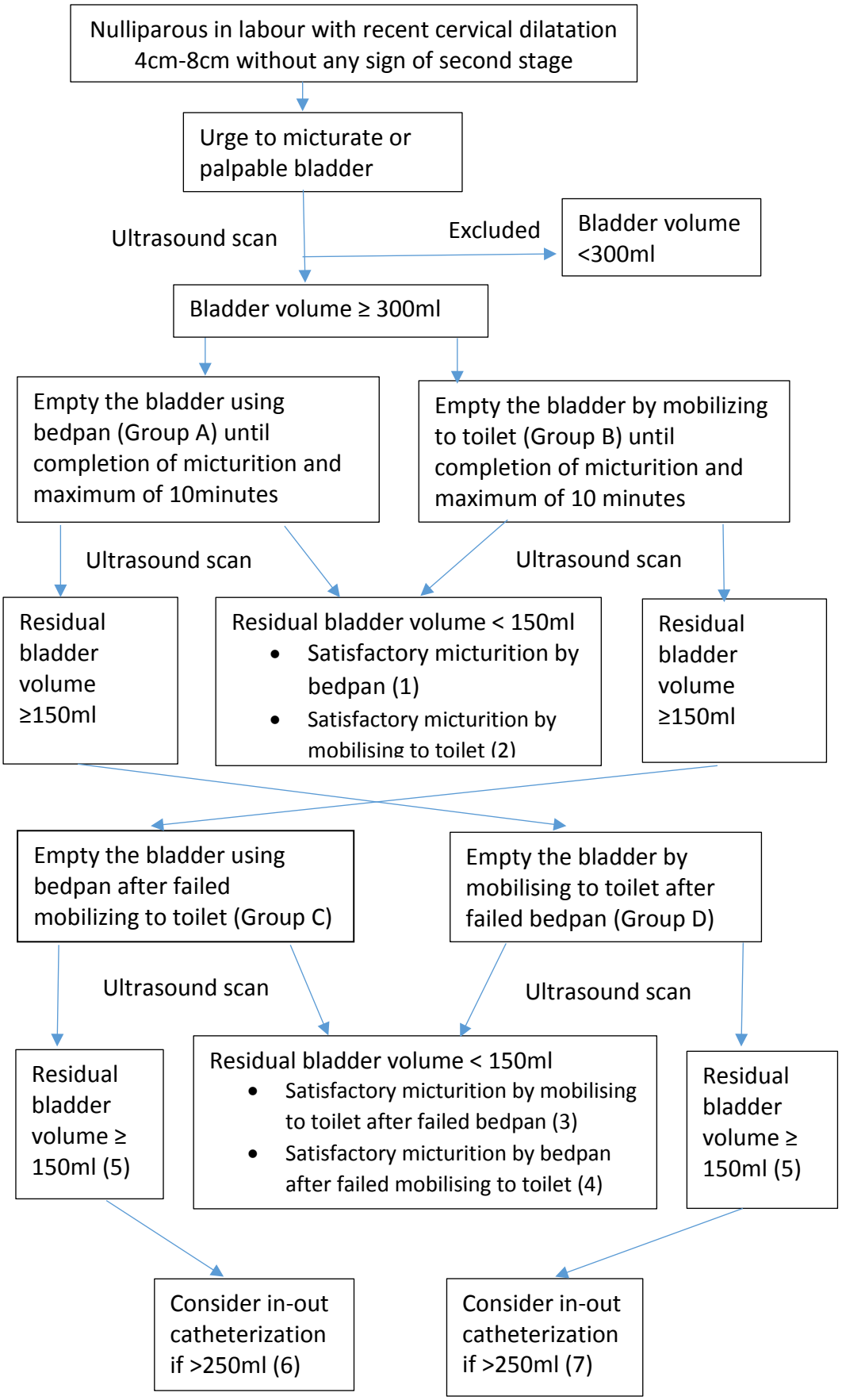
Operator accuracy:

Measurements of bladder volume will be performed by the medical officers in labour room. All of the medical officers with some basic ultrasound scan experience will receive brief training from either obstetrician or sonographer regarding scan for residual urine volume.

They need to scan on two women intrapartum for urine volume under direct supervision and their competency will then be confirmed prior embarking on the study. After that, they can perform the scan independently.

(J.W. Barrington, 2003) had mentioned that the accuracy of the bladderscan is independent of the experience of the operator towards ultrasound scan machine. Any trained individual could use the machine with no loss of efficacy.

STUDY FLOWCHART



Protocol

1. Nulliparous in labour and delivery suite will be assessed for eligibility to be recruited into this study by using **Eligibility Form** in labour room.
2. Those whom fulfilled the eligible criteria will be provided with **patient information sheet.**
3. All women were informed in detail about the study, explaining the benefits and risks.
4. Written consent will be taken from those agree to participate in this study.
5. If the patient does not agree, they will be excluded from recruitment and subsequent care will be according to standard treatment protocols.
6. The participant will be interviewed by the investigator and **Case Report Form** is filled up by the investigator.
7. The participant will only be in the study for one time throughout her labour process
8. Randomisation will be using random number generator at Random.org in random block of 6 or 9 sequence, generated by investigator who is not involved in recruitment.
9. The random allocation sequence will be placed in sealed numbered opaque envelopes for strict number order assignment to participants. Randomisation is by opening the lowest remaining numbered sealed envelope.
10. Participant will randomised to group A or group B. (Group A with bedpan, Group B with mobilising to toilet)
11. After delivery, **Outcome Form** needs to be filled in by investigator and participant.
12. Data collection by the investigator will be completed when Outcome Forms are completed by investigator and participants
13. Data entry and statistical analysis will be performed using SPSS software, version 16.0 (SPSS, Chicago,IL, USA). Values will be given as mean ±SD. Continuous data will be assessed for normality (Levene test) then compared with the use of student t test if the variable are normally distributed and Mann Whitney U test if the variable are not normally distributed. Categorial data will be compared with the use of $\chi 2$ test. Probability value of <0.05 will be considered significant.

Bedpan:

She can be lying, or sitting on the bed while micturate in the bedpan, until micturition complete and the duration given only up to 10minutes. The voided volume in the bedpan will be measured, in comparison with the residual volume by the ultrasound scan.

Mobilizing to toilet:

She will be accompanied by a healthcare provider, either by midwife or doctor to the toilet in the labour suite. She will be provided a commode chair with a bedpan beneath it. The toilet door will be closed. The duration given only up to 10minutes. The voided volume in the bedpan will be measured, in comparison with the residual volume by the ultrasound scan.

In-out Catheterization:

If she still has impaired micturition despite being providing bedpan and mobilizing to the toilet, with the residual bladder volume of more than 250ml, then to consider in-out catheterization with soft rubber catheter under aseptic technique.

Demographic characteristics:

Variable	Clinical	Bladderscan	*P* value
Age			
BMI (kg/m2)			
Ethnicity **Malay** **Chinese** **India** **Others**			
Education level			

Analysis of maternal, fetal and obstetric characteristic of women intrapartum

CASE REPORT FORM

Patient's Sticker

Study

Date of recruitment : __/__/__ (dd/mm/yy/)
Gravida:
Parity:
EDD : __/__/__ (dd/mm/yy)

Gestation age : _____

_____

Patient's characteristics

Age: ____

Latest recorded weight : _____ kg Height : _____ cm

BMI:

Education level : up to primary/ secondary/ diploma/ degree/ master/PhD

Occupation: employed/ self-employed / student / housewife/ other

Ethnicity : Malay / Chinese / Indian / Sabah ethnic / Sarawak ethnic / other

Outcome Form

1. Group:
    - Bedpan (A)
    - Mobilising to toilet (B)
    - Bedpan after failed mobilising to toilet (C)
    - Mobilising to toilet after failed bedpan (D)
2. Recent cervical dilatation (within 2 hours) upon randomisation: _____cm
3. Contraction pain: _____in 10min for ____ sec
4. Bladder volume prior randomisation by scan: _____ ml
5. Outcome (satisfactory micturiation is <150ml urine volume):
    1. Satisfactory micturition by bedpan
        a. Voided volume by measurement: _____ml
        b. Residual volume by scan: _____ml
    2. Satisfactory micturition by mobilising to toilet
        a. Voided volume by measurement: _____ml
        b. Residual volume by scan: _____ml
    3. Satisfactory micturition by mobilizing to toilet after failed bedpan
        a. Voided volume by measurement: _____ml
        b. Residual volume by scan: _____ml
    4. Satisfactory micturition by bedpan after failed mobilizing to toilet
        a. Voided volume by measurement: _____ml
        b. Residual volume by scan: _____ml
    5. Impaired micturition by bedpan and mobilizing to toilet
    6. Impaired micturition by bedpan after mobilizing to toilet and residual urine volume more than 250ml. In-out catheterization (yes/no)
    7. Impaired micturition by mobilizing to toilet after bedpan and residual urine volume more than 250ml. In-out catheterization (yes/no)
6. Duration of 2nd stage: _____min (from _____ to _____)
7. Mode of delivery :

o SVD
o Caesarean section. Indication: _____
o Vacuum / forceps. Indication: _____

8. Estimated blood loss intrapartum : _____ ml
9. Temperature:
    a. intrapartum _____^{o}C ;
    b. postnatal up to discharge _____^{o}C
10. Liquor colour : Clear / LMSL / MMSL/

11. Apgar's Score : ____ at 1 min ; ____ at 5 min
12. Arterial cord pH : ____
13. Birth Weight : ____kg
14. Required neonatal admission :
    - o No
    - o Yes : PNW/SCN/NICU/others
      Reason for admission: _____

Maternal satisfaction:

1. Prior Randomization, How do you prefer to pass urine at this point of labour
    a. Bedpan
    b. Mobilize to the toilet
    c. No preference

2. After experienced Bedpan (A) / Mobilize to the toilet (B), (before crossing over to the other method), please tick a score on the scale below to indicate your satisfaction to pass urine.

    i. I had a good experience and comfortable to pass urine.

( )	( )	( )	( )	( )
Strongly disagree	disagree	Natural	agree	strongly agree

    ii. I will recommend the method I had to my friends and relative who has same condition like me

( )	( )	( )	( )	( )
Strongly disagree	disagree	Natural	agree	strongly agree

ETHICAL CONSIDERATION

This study will be submitted to the UMMC Medical Research and Ethics committee, the local institutional review board for approval. Patient will be given an information sheet, have their oral queries addressed and written informed consent obtained to participate in this study. Confidentiality will be ensured.

SAMPLE SIZE CALCULATION

We aim to power our study for the primary outcome by Likert Scale. PS program version 3.1.2 is used to calculate sample size.

For this study, we use the relative risks of requiring in-out catheterization in the recovery room in the study of Anette B et al 2014, for mobilization to the toilet vs use of a bedpan in the bed (19% vs 54%). By assuming a more conservative presumption, we can use it as 25% vs 50%, taking alpha of 0.05, with power of 80%, 1 to 1 randomisation ratio, and applying chi square test, 58 women needed in each arm. Thus, the total of final desired sample size is 116 women.

STATISTICAL ANALYSIS

Statistical analysis will be performed using SPSS software, version 16.0 (SPSS, Chicago,IL, USA). Values will be given as mean ±SD. Continuous data will be assessed for normality (Levene test) then compared with the use of student *t* test if the variable are normally distributed and Mann Whitney U test if the variable are not normally distributed. Categorial data will be compared with the use of chi square, χ^2 test. Probability value of <0.05 will be considered significant.

Study duration:

This study will be conducted from February 2019 till October 2019.

GANNT Chart:

Year	2019										
Month	Jan	Feb	Mar	Apr	May	June	July	Aug	Sept	Oct	Nov
Literature review	////										
Proposal		////	////	////							
Ethics review					////	////					
Data collection							////	////	////		

Analysis										////	////
Writing											////

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3. *Anette B, Hansen and Karsten S. Oslsen: The Number of In-Out Catheterizations is reduced by mobilising the postoperative patient with bladder needs to the toilet in the recovery room, A Randomised Clinical Trial. Eur J Anaesthesiol 2015; 32:486-492*
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9. *Yip SK, Hin Ly, Chung TK: Effect of the duration of labour on postpartum postvoid residual bladder volume. Gynecol Obstet Investig 1998; 45 (3): 177-180*
10. *Muellner SR (1938) Physiological bladder changes during pregnancy and the puerperium. J Urol 41:691*

Appendix III: ELIGIBILITY SCREENING, RECRUITMENT AND RANDOMISATION FORM

STUDY TITLE:
Micturition in the toilet environment compared with the bedpan in nulliparous in labour – A Randomized Control Trial

PATIENT'S ID STICKER:

DATE:
Clinicians kindly go through the flow chart below for all women who admitted to labour suite for delivery prior to recruitment to the study. If at any point patient does not fulfill the inclusion or exclusion criteria, identify by **X** in the boxes provided. If patient fulfills all the criteria, proceed with recruitment. Kindly identify by **X** if patient refuses to participate in the study.

Woman who admitted to labour suite for delivery. ☐

Inclusion criteria: ☐

- Aged 18 years and above
- Nulliparous (first labours and no prior delivery beyond 20weeks of gestation) in labour with recent cervical dilatation (within 2 hours) of 4cm - 8cm and without any external sign of second stage and rectal pressure
- Membrane ruptured
- Singleton live fetus
- Cephalic presentation
- Contraction pain of at least 3 in 10 minutes lasted for at least 15 sec
- Urge to micturate and/or palpable bladder
- Bladder volume of at least 300ml by ultrasound scan

Exclusion criteria: ☐

- Any condition that is contraindicated for vagina delivery (e.g. Placenta previa major)
- Neurological disease involving bladder dysfunction
- Intact membrane as it can cause inaccuracy of the bladder scan
- Epidural analgesia in labour
- History of repeated (>2 during antenatal period) urinary tract infections
- Lower segment uterine fibroid
- No indication risk of immediate delivery (external sign of second stage and rectal pressure)

Not Eligible ☐ Eligible but declined ☐

Randomized to RANDOMISATION ID: _____

Appendix IV: PARTICIPANT INFORMATION SHEET AND INFORMED CONSENT FORM

1. Title of study:

Micturition in the toilet environment compared with the bedpan in nulliparous in labour – A Randomized Control Trial

(Public Title: To compare the ability of passing urine by either using bedpan or mobilising to toilet for women in their first labours process)

2. Name of investigator and institution:

Professor Dr. Tan Peng Chiong, Dr. Chong Wen Kiat,
Department of Obstetrics and Gynaecology UMMC

3. Introduction:

You are invited to participate in a research study because you have been planned for delivery in labour suite. The details of the research trial are described in this document. It is important that you understand why the research is being done and what it will involve. Please take your time to read through and consider this information carefully before you decide if you are willing to participate. Ask the study staff if anything is unclear or if you like more information. After you are properly satisfied that you understand this study, and that you wish to participate, you must sign this informed consent form. To participate in this study, you may be required to provide your doctor with information on your health history; you may harm yourself if you are not truthful with the information provided.

Your participation in this study is **voluntary**. You do not have to be in this study if you do not want to. You may also refuse to answer any questions you do not want to answer. If you volunteer to be in this study, you may withdraw from it at any time. If you withdraw, any data collected from you up to your withdrawal will still be used for the study. Your refusal to participate or withdrawal will not affect any medical or health benefits to which you are otherwise entitled.

This study has been approved by the Medical Research and Ethics Committee, Ministry of Health Malaysia.

4. What is the purpose of the study?

In view the length of labour may vary, especially for women with first labours (nulliparous) average can last about 8 hours up to 18 hours. Thus the ability to pass urine needs to be monitored as most of the time in view spontaneous passing urine may become progressively difficult by the advancing baby's head.

By providing either bedpan or go to toilet to pass urine during labour, some may think that there's no different in term of the ability to pass urine satisfactory. Thus, the purpose of this study is to see the effectiveness to pass urine by mobilizing them (women with first labours) to toilet as compared with using bedpan in nulliparous in labour.

5. What will happen if I decide to take part?

You will be provided either using bedpan or mobilizing to toilet to pass urine when your recent vaginal dilatation between 4cm – 8cm. As long as there is no external sign of

second stage (*external* genitals or anus begin to bulge out during contractions) or rectopressure (have the urge to push/bear down), you are generally safe to mobilize and the risk to deliver in the toilet is very small. The measure that we will be taken to further minimize the risk as stated below in Section 10 and Section 12.
The duration that you can pass urine in the toilet or in the bedpan will only be limited up to 10 minutes. To consider as satisfactory urination when your residual urine volume is less than 150ml by ultrasound scan after voiding. Otherwise, if your residual urine volume is more than 150ml, which mean the urination is still unsatisfactory, then you will be crossed over to the other arm to pass urine (i.e. to pass urine in the toilet if unable to pass urine in the bedpan, and vice versa). If both methods that u had tried still failed, and the remaining urine volume by scan is more than 250ml, then we might consider to put a urine tube just for in-out to empty your bladder.

A questionnaires will be given to you and you will be explained on how to fill up the questionnaires. Your care during labour will be same like any other women, and only another alternative for bladder needs will be provided depends on which group you are allocated to. Routine cares after your delivery will be the same as others who did not participate in the study. After the delivery you are required to fill up the questionnaires. A study staff will approach you and assist you in filling up the questionnaires.

6. When will I receive the trial product and how should it be kept?

No trial product will be provided.

7. What are my responsibilities when taking part in this study?

It is important that you answer all of the questions asked by the study staff honestly and completely.

It is very important that your study doctor be informed very rapidly of any eventual changes to your health during your participation in the study. For your own security, it is important that you follow your study doctor's instructions throughout the entire duration of the study.

8. What kind of treatment will I receive after my participation in the trial?

No study product will be given to you at the end of your participation in the study. Whether you complete the study or withdraw early, your doctor will discuss the best alternatives for your future treatment with you.

9. What are the potential risks and side effects of being in this study?

You may experience difficulty to void either by bedpan or mobilizing to toilet. In-out catheterization will only be carried out if both of the methods has failed and with significant urine volume.

Small risk the baby will be delivered in the toilet or may experience fall if mobilizing. However, companion by the family member (e.g. partner) and support from health care provider (e.g. midwife/ trainee doctor) can further minimize the risks.

Please ask your study doctor if you need more information on risks and side effects. The trial staff will inform you in a timely manner about any new findings or changes about the study procedure which may affect your health or willingness to continue in this study. Where necessary, you may be asked to re-consent to participate.

10. What are the benefits of being in this study?

There may or may not be any benefits to you. Information obtained from this study will help improve the treatment or management of other patients with the same disease or condition.

11. What if I am injured during this study?

If you are injured as a result of being in this study, you should contact your study doctor. UMMC will provide immediate action or assistance if you encounter any problem during the study, as per UMMC standard management protocol. You do not lose any of your legal rights to seek compensation by signing this form.

12. What are my alternatives if I do not participate in this study?

You do not have to participate in this study to get treatment for your pregnancy process. The study doctor will discuss in more details the benefits and risks of those treatments with you.

13. Who is funding the research?

The research is self-funded by the researcher.

14. Can the research or my participation be terminated early?

The study doctor or UMMC may due to concerns for your safety, stop the study or your participation at any time. If the study is stopped early for any reason you will be informed and arrangements made for your future care. You may be asked to attend a final follow-up visit.

15. Will my medical information be kept private?

All your information obtained in this study will be kept and handled in a confidential manner, in accordance with 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 and auditors, the sponsor or 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 and may be transmitted outside the country for the purpose of analysis, but your identity will not be revealed at any time.

16. Who should I call if I have questions?

If you have any questions about the study or if you think you have a study related injury and you want information about treatment, please contact the study doctor,
Dr. Chong Wen Kiat (016-2517083).

If you have any questions about your rights as a participant in this study, please contact: The Secretary, Medical Research & Ethics Committee, Ministry of Health Malaysia, at telephone number 03-2287 4032.

INFORMED CONSENT FORM

Title of Study:
Micturition in the toilet environment compared with the bedpan in nulliparous in labour – A Randomized Control Trial

By signing below I confirm the following:

- I have been given oral and written information for the above study and have read and understood the information given.
- I have had sufficient time to consider participation in the study and have had the opportunity to ask questions and all my questions have been answered satisfactorily.
- I understand that my participation is voluntary and I can at any time free withdraw from the study without giving a reason and this will in no way affect my future treatment. I understand the risks and benefits, and I freely give my informed consent to participate under the conditions stated. I understand that I must follow the study doctor's (investigator's) instructions related to my participation in the study.
- I understand that study staff, qualified monitors and auditors, the sponsor or its affiliates, and governmental or regulatory authorities, have direct access to my medical record in order to make sure that the study is conducted correctly and the data are recorded correctly. All personal details will be treated as STRICTLY CONFIDENTIAL

  I will receive a copy of this subject information/informed consent form signed and dated to bring home.
- I **agree/disagree*** for my family doctor to be informed of my participation in this study. *(*delete which is not applicable)*

Subject:

Signature:		I/C Number:	
Name:		Date:	

Investigator conducting informed consent:

Signature:		I/C Number:	
Name:		Date:	

Impartial witness: *(Required if subject is illiterate and contents of patient information sheet is orally communicated to subject)*

Signature:		I/C Number:	
Name:		Date:	