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To compare the ability to pass urine by either using a bedpan or mobilising to the toilet for women in their first labour

Submission date
11/06/2019

Recruitment status
No longer recruiting

Registration date
17/07/2019

Overall study status
Completed

Last Edited
07/11/2022

Condition category
Pregnancy and Childbirth

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
The purpose of this study is to see the effectiveness to empty the bladder by mobilizing nulliparous in labour with bladder needs to the toilet as compared with using a bedpan. The duration of the first stage of labour varies, the average for nulliparous might last about 8 hours and can be up to 18 hours in labour. The ability to pass urine needs to be monitored for time to time during the first stage of labour, in view spontaneous voiding may become progressively difficult by the advancing fetal head.

From the previous practice, it was preferable to provide bedpan for the bladder needs in women in labour. However, for 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 the toilet instead of a bedpan.

Thus, it is believed that by offering the nulliparous in labour to mobilize to the 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.

The research hypothesis is by mobilising to the toilet for micturition, can improve the urination as compared with a bedpan for nulliparous in labour.

Who can participate?
Women in the first stage of labour with the opening of the neck of the womb of 4cm to 8cm and with a urine bladder volume of at least 300ml as determined by ultrasound scan.

What does the study involve?
This study involves bladder care for women in their first stage of labour, whether or not by mobilizing and pass urine in the toilet is more effective than just providing them with a bedpan.

What are the possible benefits and risks of participating?
The patient may experience difficulty in voiding either by bedpan or mobilizing to the toilet. In-out catheterization will only be carried out if both of the methods have failed and with significant urine volume by scan (more than 250ml)
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 supervision from health care provider (e.g. midwife/ trainee doctor) can further minimize the risks.

Where is the study run from?
The University Malaya Medical Centre.

When is the study starting and how long is it expected to run for?
January 2019 to November 2019

Who is funding the study?
Investigator-initiated and funded

Who is the main contact?
Dr Chong Wen Kiat
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Contact information

Type(s)
Public

Contact name
Dr Chong Wen Kiat

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
2019330-7272

Study information

Scientific Title
Micturition in the toilet environment compared with the bedpan in nulliparous in labour: a randomized cross over trial

Acronym
N/A

Study objectives
Offering mobilizing to the toilet instead of bedpan can improve micturition in nulliparous in labour.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/07/2019, University Malaya Medical Centre (Jalan Universiti, Lembah Pantai, 50603 Kuala Lumpur, Malaysia; iresearch@ummc.edu.my; +60133902676), ref: 2019330-7272.

Study design
Randomized cross over trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Bladder needs or micturition for nulliparous in labour

Interventions
Nulliparous in labour with recent cervical dilatation 4 cm - 8 cm without any sign of second stage are recruited when they have the urge to micturate or palpable bladder, with >300ml of bladder volume by scan. They are randomised to either use the bedpan or mobilise to the toilet. Micturition is considered satisfactory if residual urine volume <150 ml. If ≥150ml, the participant crosses over to the other arm. In-out catheterisation is considered if both methods fail and residual urine volume is >250 ml.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Satisfactory micturition (residual urine volume < 150 ml) is measured using an ultrasound machine prior to and after voiding.

Key secondary outcome(s))
1. Frequency of in-out catheterization during the first stage of labour.
2. Duration of the second stage of labour (from the onset of full cervical dilatation to delivery of the baby).
3. Number of instrumental delivery (whether patient ends up with instrumental delivery).

4. Number of patients that undergo cesarean section.
5. Estimated blood loss during delivery.
6. Maternal satisfactory is measured using the Scale for Measuring Maternal Satisfaction prior to randomisation and prior to cross-over.

Completion date
30/11/2019

Eligibility

Key inclusion criteria
Current inclusion criteria as of 29/07/2019:
1. Aged 18 years and above
2. Nulliparous (first labour and no prior delivery beyond 20 weeks of gestation) in labour with recent cervical dilatation (within 2 h) of 4 cm – 8 cm and without any external sign of second stage and rectal pressure
3. Membrane ruptured
4. Singleton live fetus
5. Cephalic presentation
6. Contraction pain of at least 3 in 10 min lasting for at least 15 s
7. Urge to micturate and/or palpable bladder
8. Bladder volume of at least 300 ml by ultrasound scan
9. Participant has not previously experienced using a bedpan or urine catheter to pass urine

Previous inclusion criteria:
1. Aged 18 years and above
2. Nulliparous (first labour and no prior delivery beyond 20 weeks of gestation) in labour with recent cervical dilatation (within 2 h) of 4 cm – 8 cm and without any external sign of second stage and rectal pressure
3. Membrane ruptured
4. Singleton live fetus
5. Cephalic presentation
6. Contraction pain of at least 3 in 10 min lasting for at least 15 s
7. Urge to micturate and/or palpable bladder
8. Bladder volume of at least 300 ml by ultrasound scan

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Total final enrolment
116

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

Date of first enrolment
22/07/2019

Date of final enrolment
31/10/2019

Locations

Countries of recruitment
Malaysia

Study participating centre
University Malaya Medical Centre
Labour and Delivery Suites
Women and Children Health Complex
Kuala Lumpur
Malaysia
50603

Sponsor information

Organisation
University Malaya Medical Centre

ROR
https://ror.org/00vkrxq08

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Chong Wen Kiat (jeffchong1985@gmail.com) and Prof Dr. Tan Peng Chiong (pctan@um.edu.my). The estimated duration that requires data collection is about 3 months. The questionnaires and the written consent from participants will be obtained as stated in the study protocol.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		04/11/2022	07/11/2022	Yes	No
Protocol file		16/07/2019	18/07/2019	No	No