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Self bladder emptying compared to insertion of indwelling catheter, to empty the bladder for caesarean section

Submission date
24/12/2021

Recruitment status
No longer recruiting

Registration date
31/12/2021

Overall study status
Completed

Last Edited
21/01/2022

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
A number of studies have provided information that self-bladder emptying (peeing in the toilet) from before Caesarean section and through recovery reduces the risk of urine infection without causing any problem during surgery (no bladder injury observed) or urination difficulty in the immediate recovery period.
However, one different type of study finds that when the catheter is removed immediately after the Caesarean is completed, 13.6% have difficulty peeing and need the catheter to be put back for a short time.
This is a study to compare the performances between peeing in the toilet (self-bladder emptying) with urinary bladder catheter placement at planned caesarean section to improve recovery and increase patient satisfaction.
The aim of this study is to evaluate the trial interventions as there is uncertainty about which is better or they may be equivalent. Information obtained from this study will help guide the management of future patients in similar circumstances.

Who can participate?
Participants include women aged 18 years and above, carrying a single healthy fetus (>37 weeks of gestation), who is planned to deliver by caesarean section.

What does the study involve?
Participants will be divided into two groups, one will urinate in the toilet and another group will have a urinary catheter inserted before surgery. The main outcome of this study is the rate of postpartum urinary retention (inability to pass urine after surgery) and participants' satisfaction with the given intervention.

What are the possible benefits and risks of participating?
There may or may not be any benefits to the participants. Information obtained from this study will help guide the management of future patients in similar circumstances.
For those allocated to self-emptying of bladder the specific risks are:
1. Operating field issue because the bladder is too filled up during surgery – the catheter will be

inserted after the operation has begun
2. Injury to bladder – it will be repaired and the catheter has to be left in for about 1-2 weeks
3. Unable to pee immediately after surgery – catheter in and out or left in for up to 24 hours
For those allocated to the placement of a catheter the specific risks are:
1. Urine infection
2. Slower overall recovery from Caesarean section
3. After catheter removal, initial urination may be more uncomfortable and less satisfactory

Where is the study run from?
University Malaya Medical Centre (UMMC) (Malaysia)

When is the study starting and how long is it expected to run for?
September 2021 to May 2023

Who is funding the study?
University Malaya Medical Centre (UMMC) (Malaysia)

Who is the main contact?
Dr Nabila Arfah Mohd Yassin
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Contact information

Type(s)
Principal investigator

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Additional identifiers

Protocol serial number
MREC UMMC ID NO: 2021114-10756

Study information

Scientific Title

Self bladder emptying compared with catheter placement for planned caesarean section: a randomised controlled trial

Study objectives
1. Pre-caesarean section indwelling bladder catheterisation vs self-voiding is superior with respect to post-partum urinary retention (PPUR)
2. Self-voiders are more satisfied with their bladder care compared to having an indwelling bladder catheter

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/11/2021, Medical Research Ethics Committee of University Malaya Medical Centre (Lembah Pantai, 59100 Kuala Lumpur, Malaysia; +60 3-79493209/2251; iresearch@ummc.edu.my), ref: 2021114-10756

Primary study design
Interventional

Study design
Single-center interventional randomized controlled trial

Study type(s)
Quality of life

Health condition(s) or problem(s) studied
Women undergoing planned caesarean section

Interventions
Participants will be randomised into two arms, the self-emptying of the bladder arm or the indwelling bladder catheter arm.

Patients randomised to self-emptying of the bladder arm will be asked to empty their bladder at OT call in the ward toilet before despatch to the operation theatre (in case of delay in starting of surgery they will be asked again to pass urine in the OT, ideally within 1 hour prior to start of surgery as per Senanayake et al).

Patients randomised to indwelling bladder catheter will have their catheter inserted as per usual practice under aseptic technique using Foley catheter size 16F, after regional anaesthesia has been given in the operating theatre. The Foley catheter will be removed the next day according to current UMMC standard practice.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Post-partum urinary retention (PPUR) rate measured using bladder scan at hospital discharge
2. Maternal satisfaction with their allocated peri-caesarean bladder care measured using the Verbal Numeric Rating Scale (VNRS) at discharge

Key secondary outcome(s)
1. Intraoperative outcomes measured using case report form – data collected after caesarean section is done:
1.1. Surgical field impairment (Yes/No)
1.2. Distressed catheterization (need for catheterization during caesarean section) (Yes/No)
1.3. Operative blood loss (in milliliters)
1.4. Bladder injury (Yes/No)
1.5. Duration of surgery (in minutes)
2. Postoperative outcomes measured using case report form at 24 hours post-surgery:
2.1. Urinary tract infection with urine culture and sensitivity test at 24 hours post-surgery
2.2. Lower urinary tract symptoms (LUTS) measured with the International Prostate Symptom Score (IPSS) questionnaire upon discharge
2.3. Time to first bowel flatulence
2.4. Time to first satisfactory breastfeeding experience
2.5. Time to first satisfactory urination
2.6. Time to first satisfactory ambulation
2.7. 11-point 0-10 Verbal Numeric Rating Scale (VNRS) pain score at first post-caesarean urination
2.8. Length of hospital stay post-surgery (from operation to discharge)
2.9. 11-point 0-10 VNRS pain score upon movement at discharge

Completion date
31/05/2023

Eligibility

Key inclusion criteria
1. Planned caesarean section
2. Age 18 years and above
3. Gestational age (supported by dating ultrasound) ≥37 weeks
4. Singleton pregnancy
5. Reassuring fetal heart rate tracing

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Female

Key exclusion criteria
1. Patients with evidence of urinary tract infection or recurrent antenatal UTI
2. Presence of large (>4 cm) ovarian or uterine masses

3. Anticipated pelvic adhesion
4. Anticipated difficult surgery or prolonged surgery time such as cases of placenta previa or accreta spectrum
5. Patients with severe pre-eclampsia or any other conditions requiring postoperative monitoring of urinary output

Date of first enrolment
01/01/2022

Date of final enrolment
31/03/2023

Locations

Countries of recruitment
Malaysia

Study participating centre
University Malaya Medical Centre
Lembah Pantai
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

Current individual participant data (IPD) sharing statement as of 21/01/2022:
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Nabila Arfah Mohd Yassin (nabila.arfah@ummc.edu.my). All the data collected will be available 6 months after publication of trial reports, subject to institutional review board approval.

Previous individual participant data (IPD) sharing statement:
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Nabila Arfah Mohd Yassin (nabila.arfah@ummc.edu.my). All of the participant data collected during the trial, after deidentification, will be available from 6 months after the end of recruitment until 10 years after the end of recruitment, for anyone who wishes to access the data for any purpose upon request/contacting the investigator. The study protocol, statistical analysis plan, informed consent form, and clinical study report will be available. Consent will be taken from participants, and they will be informed regarding this matter in the patient information sheet - anonymised trial data may be released to other researchers in the future, however, their identity will not be revealed. Anonymisation of trial data will be carried out before it is released to other researchers in the future as permitted by the Ethics Committee.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1	05/11/2021	29/12/2021	No	Yes
Protocol file	version 1.0	05/11/2021	29/12/2021	No	No