ISRCTN11162423 https://doi.org/10.1186/ISRCTN11162423

Continuous compared to intermittent bladder catheterisation for epidural analgesia in labour

Submission date
22/03/2024

Recruitment status
No longer recruiting

Registration date
04/04/2024

Overall study status
Completed

Last Edited
02/04/2024

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
The pain that women experience during labour varies greatly from little to extremely distressing pain. Once an epidural catheter has been inserted through the spine into the epidural space, local anaesthetic agents are injected to numb the nerves carrying pain signals to the brain. Epidural analgesia is considered to be the most efficient method of pain relief during labour. In high-income countries rates for labour epidural analgesia are at 10% to 64%. Nerve signals controlling urination are also affected by the epidural, such that 30% of the patients with epidural analgesia find it difficult to pass urine during labour. To overcome this problem, after an epidural is placed, the bladder can be emptied by continuous drainage with a catheter left in place for the duration of labour and delivery or periodically emptied at least every 4 hours. The evidence on which is the better method to effectively drain the bladder is inconclusive. Preliminary data suggest that of the two methods, continuous drainage compared to periodic emptying, may reduce the need for caesarean delivery but may increase the risk of bleeding at delivery. This study aims to compare continuous to periodic bladder drainage for bladder care during epidural analgesia in labour, primarily on the outcomes of caesarean section and bleeding at delivery. Other labour and delivery, and baby outcomes will also evaluated.

Who can participate?
Adult women in labor aged between 18 and 45 years old after the successful commencement of epidural analgesia

What does the study involve?
Once epidural analgesia is successfully administered during labor, participants will be divided into two groups based on their preference for bladder catheterization. For those opting for continuous catheterization, a 16F Foley catheter will be inserted using sterile techniques, with its balloon inflated to 10 ml to maintain its position until after delivery, including perineal repair if necessary. Alternatively, participants preferring intermittent catheterization will undergo in-and-out catheterization every 4 hours, or more frequently if their bladder is notably distended or they feel the urge to void. This method ensures bladder comfort and management during labor. Randomization into either group will be conducted through opaque sealed numbered

envelopes, with the sequence predetermined using an online generator in blocks of 4 or 8, facilitated by an impartial investigator. Regardless of group allocation, all participants will receive standard labor care throughout the study.

What are the possible benefits and risks of participating?
The two interventions evaluated in this study are commonly applied as standard care to ensure bladder emptying after epidural analgesia during labour. No major harm is anticipated with either intervention. Available data on adverse outcomes do not indicate a major difference between the study interventions. Of the study's primary outcomes of caesarean delivery and postpartum haemorrhage, the eventual result could be as hypothesised, equivalent or even contrary to our hypothesis.

Where is the study run from?
University Malaya Medical Centre

When is the study starting and how long is it expected to run for?
September 2023 to May 2025

Who is funding the study?
University Malaya Medical Centre

Who is the main contact?
Prof Tan Peng Chiong, pctan@um.edu.my

Contact information

Type(s)
Public, Scientific, Principal Investigator

Contact name
Dr Rahmah Rashidah Binti hashim

Contact details
No58, Lorong Au1c/J, Taman Keramat permai
Kuala Lumpur
Malaysia
54200
+60 (0)127417190
s2030498@siswa.um.edu.my

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Continuous compared to intermittent bladder catheterisation for epidural analgesia in labour: a randomized controlled trial

Study objectives
Comparing intermittent to continuous bladder catheterization for labour epidural analgesia:
1. Caesarean delivery is reduced and 2. Postpartum haemorrhage is increased.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 21/02/2024, Medical Research Ethics Committee Universiti Malaya Medical Centre (Lembang Pantai, Kuala Lumpur, 59100 , Malaysia; +60 (0)3-79493209/2251; ummc-mrec@ummc.edu.my), ref: 20231229-13192

Study design
Single-centre interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital, Medical and other records

Study type(s)
Treatment, Efficacy

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Epidural analgesia in labour

Interventions
After the successful commencement of epidural analgesia

1. For participants randomised to continuous bladder catheterisation, the 16F Foley catheter will be inserted under a standard aseptic technique. The balloon will be inflated to 10 ml. The catheter will be left in place until after delivery (to cover perineal repair).
OR

2. For participants randomised to intermittent bladder catheterisation, in and out bladder catheterisation will be performed under a standard aseptic technique every 4 hours (or earlier if the bladder is clinically distended or there is the urge to void).

Method

Women who requested epidural analgesia in labor will be assessed for eligibility. Potentially eligible patients will be given the 'Patient Information Sheet', encouraged to ask about the study and have their queries answered. After the successful epidural, written informed consent patient will be obtained, and randomisation performed without delay to receive intermittent (IC) or continuous indwelling bladder catheterization (CC).

Randomisation will be by the opening of an opaque sealed numbered envelope containing the allocated intervention. The randomisation sequence will be generated using an online generator in blocks of 4 or 8 by an investigator not involved in trial recruitment. The lowest numbered envelope will be opened for the newest recruit.

Standard labour care will be provided to all participants.

Intervention Type
Procedure/Surgery

Primary outcome measure
The following primary outcome variables will be measured using data collected in medical notes during the delivery:
1. Delivery blood loss (≥ 500 ml)
2. Cesarean delivery

Secondary outcome measures
The following secondary outcome variables will be measured using data collected in medical notes during the delivery:
1. Epidural insertion to second stage interval
2. Epidural insertion to delivery interval
3. Epidural insertion to removal interval
4. Epidural insertion to discharge interval
5. Mode of delivery (indication for caesarean)
6. Perineal condition
7. Estimated delivery blood loss
8. Birth weight
9. Apgar score at 1 and 5 minutes
10. Umbilical cord artery blood pH
11. Neonatal intensive care admission (and indication)
12. Satisfaction with allocated bladder catheterisation regimen 0-10 NRS

Overall study start date
01/09/2023

Completion date
01/05/2025

Eligibility

Key inclusion criteria
1. Received intrapartum epidural analgesia
2. 1st stage of labour (at least 3 cm dilated and 2 contractions every 10 minutes)
3. ≥ 37 weeks gestation
4. Age ≥18 years old
5. Singleton fetus
6. Cephalic presentation
7. Reassuring fetal heart rate tracing

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
45 Years

Sex
Female

Target number of participants
434 samples needed which include 217 women are needed in each arm.

Key exclusion criteria
1. Latex allergy
2. BMI ≥35
3. Indwelling urinary catheter required
4. Cannot communicate in English or Malay

Date of first enrolment
01/05/2024

Date of final enrolment
30/04/2025

Locations

Countries of recruitment
Malaysia

Study participating centre
University Malaya Medical Centre
Jalan Universiti, Lembah Pantai
Petaling Jaya

Malaysia
59100

Sponsor information

Organisation
University Malaya Medical Centre

Sponsor details
Lembah Pantai
Petaling Jaya
Malaysia
59100
+60 (0)379494422
pctan@um.edu.my

Sponsor type
University/education

Website
https://www.ummc.edu.my/#

ROR
https://ror.org/00vkrxq08

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Universiti Malaya

Alternative Name(s)
University of Malaya, University Malaya, Malayan University, UM

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Malaysia

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
30/11/2025

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from Prof Tan Peng Chiong, pctan@um.edu.my subject to institutional review board approval.

IPD sharing plan summary
Available on request