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Speculum compared to digital insertion of the Foley catheter for labour induction in nulliparas

Submission date
10/11/2017

Recruitment status
No longer recruiting

Registration date
15/11/2017

Overall study status
Completed

Last Edited
01/06/2020

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Foley catheter (tube) insertion is a well-established method of inducing labour. It is recommended by the World Health Organisation (WHO) and is widely used in Malaysia as well as in developed countries. There are two methods of Foley catheter insertion, namely using a speculum (device) or digitally (with fingers). The speculum method is more commonly used but a recent small study suggests digital insertion may be better tolerated. There is no currently recommended method of insertion and care providers used a method based on personal preference. The aim of this study is to assess the ease and tolerability of digital compared to speculum insertion of Foley catheter for induction of labour.

Who can participate?
Pregnant women aged 18 and over

What does the study involve?
Participants are randomly allocated to either speculum or digital insertion of the Foley catheter. Following successful insertion, standard induction of labour is carried out in both groups. The time taken for successful insertion, failure of insertion, and associated pain are assessed in both groups.

What are the possible benefits and risks of participating?
No major benefits or risks are expected from the proposed interventions. If the participant is allocated to the superior method of insertion, her insertion will be easier and better tolerated. It is possible that both methods may be equivalent. No additional risks are expected expected to routine Foley catheter induction of labour.

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

When is the study starting and how long is it expected to run for?
December 2017 to December 2018

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

Who is the main contact?
Dr Hang Min Chia

Contact information

Type(s)
Scientific

Contact name
Dr Hang Min Chia

Contact details
Pusat Perubatan Universiti Malaya,
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Additional identifiers

Protocol serial number
2017104-5636.V1

Study information

Scientific Title
Speculum compared to digital insertion of the Foley catheter for labour induction in nulliparas: a randomised controlled trial

Acronym
SPEDIG

Study objectives
Digitally guided insertion of Foley catheter through the cervix for induction of labour is easier and better tolerated than visually guided insertion using the vaginal speculum.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Malaya Medical Research Ethics Committee (UMMC-MREC), 25/10/2017, ref: 2017104-5636

Study design
Single-centre randomised controlled trial with no blinding

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Induction of labour

Interventions
Randomisation is by the opening of sealed opaque and numbered envelope with lowest available envelope assigned in strict order. Randomisation sequence will be generated using a random number generator at Random.org in random block of 4 or 8 sequence, generated by investigator who is not involved in recruitment.

Participants will be randomised into two groups: the digital group or the speculum group. Only specified investigators will perform the intervention using a standardised protocol
In both group, participants will be placed on lithotomy position.
1. In the digital group, the Foley catheter tip will be guided through the cervical os by operator's gloved index and middle fingers in the vagina with aid of a water-soluble lubricant
2. In the speculum group, a sterile Cusco speculum lubricated with a water-soluble lubricant will be inserted into the vagina and adjusted to visualise cervix, a sponge forcep will be used to guide Foley catheter tip through the cervical os.

In both arms, after the catheter tip has been passed through the cervical canal, the Foley balloon will then be inflated with 60mls of sterile water and gently retracted till it meets resistance.The external end of the catheter will be taped without tension to the medial aspect of the women's thigh. In the event of a failed insertion, cross over to the other method will apply. Following successful insertion of the Foley catheter, standard institutional care applicable to Foley catheter labour induction shall apply.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Measured during and at the end of the first attempt of the procedure, process will not be more than 6 minutes:
1. Time taken to successful insertion (first attempt): measurement of insertion time using a stop watch, begins when the operator's finger or speculum entered the vagina and ended at full inflation of the catheter balloon
2. Failure of insertion (first attempt)
3. Pain score associated with the Foley catheter insertion, measured using Visual Numerical Rating Scale (VNRS) scored from 0 to 10, with higher score denoting greater pain, assessed immediately after the first insertion attempt

Key secondary outcome(s))
Maternal outcomes:
1. Preference of insertion method: question will be asked after intervention (insertion)
2. Use of additional method(s) for cervical ripening, obtained from patient's medical record
3. Insertion-to-balloon expulsion or removal interval, obtained from patient's medical record
4. Epidural analgesia usage, obtained from patient's medical record

5. Oxytocin for labour induction or augmentation (not for third stage), obtained from patient's medical record
6. Induction to delivery interval, obtained from patient's medical record
7. Mode of delivery and indication for operative delivery, obtained from patient's medical record
8. Estimated blood loss, obtained from patient's medical record
9. Maternal satisfaction with their care from intervention to birth, assessed within 24 hours of delivery
10. Fever: single or more readings of temperature ≥38oC (intrapartum and day 1 postpartum), diagnosis of chorioamnionitis or endometritis, obtained from patient's medical record

Neonatal outcomes, obtained from patient's medical record:
1. Apgar score
2. NICU admission
3. Birth weight
4. Cord pH

Completion date
31/12/2018

Eligibility

Key inclusion criteria
1. Aged 18 years and above
2. Nulliparous women
3. Gestational age of > 37 weeks at enrollment
4. Fetus in cephalic presentation
5. Singleton fetus
6. Reassuring pre-induction fetal cardiotocography
7. Unfavourable cervix (Bishop score ≤ 5)
8. Intact membrane
9. Able to read and understand informed consents and questionnaires

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Total final enrolment
86

Key exclusion criteria
1. Previous use of an induction or preinduction agent
2. Suspicion of chorioamnionitis or clinical genital tract infection
3. Allergy to latex
4. Known gross fatal anomaly

Date of first enrolment
01/12/2017

Date of final enrolment
31/12/2018

Locations

Countries of recruitment
Malaysia

Study participating centre
University of Malaya Medical Centre
Lembah Pantai
Kuala Lumpur
Malaysia
59100

Sponsor information

Organisation
University of Malaya

ROR
https://ror.org/00rzspn62

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Department of Obstetrics and Gynecology, University of Malaya Medical Centre

Results and Publications

Individual participant data (IPD) sharing plan

The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	29/05/2020	01/06/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes