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A randomized trial of labour induction using the Foley catheter of different bores (French sizes 16, 22 and 28: 1 French size equals 0.33 mm)

Submission date
29/10/2017

Recruitment status
No longer recruiting

Registration date
13/12/2017

Overall study status
Completed

Last Edited
27/10/2022

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
Induction of labour (IOL) is a common procedure that starts labour artificially. This may occur is a baby is overdue, there is a health problem or if the water has been broken to ensure the baby and mothers wellbeing. IOL can be done by inserting a tablet or get into the vagina. This can be accomplished with Foley catheter. The Foley catheter is a flexible tube that can be inserted into the vagina. World Health Organization recommends its use for IOL. It is currently in use in UMMC and in many other hospitals in Malaysia for IOL. The Foley catheter size that is used for IOL ranged from 14 F to 30 F. No clinical guidelines recommend an optimal size to use as no study has been performed comparing different sizes. It could be possible the IOL with larger size of Foley catheter in a woman with an unfavourable cervix will be easier to insert and will result in less insertion time. Less insertion time will cause less pain to participant and higher successful rate. The aim of this study is to find a catheter size with the easiest insertion characteristic.

Who can participate?
Women aged 18 and older who have scheduled to have labour induced.

What does the study involve?
Participants are randomly allocated to one of three groups. Those in the first group have a 16 F catheter inserted. Those in the second group have the 22 F used. Those in the last group use the 28 F Foley catheter. The Foley catheter is guided through the internal os by operator's hand and fingers lubricated with water soluble lubricant. If the digital insertion is unsuccessful, the catheter of the same bore is inserted using a sterile Cusco speculum lubricated with water soluble lubricant into the vagina and adjusted to visualise cervix, a sponge forceps will be used to guide Foley catheter into the cervical canal, through the internal os. Standard UMMC labour induction and labour care will apply after the attempt to use the Foley catheter whether it is eventually successful inserter or otherwise. The catheter insertion times and patient pain scores are assessed.

What are the possible benefits and risks of participating?
There are no notable benefits or risks associated with participation. It possible all catheter bore

may be equivalent. As it is not known which catheter bore may be superior in ease of insertion or best effect in the labour induction process, you may be assigned to a study arm that may have the best or worst outcomes. Serious complications and major benefits are not anticipated in this study.

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?
July 2017 to December 2018

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

Who is the main contact?
Dr Rohaida Binti Zakaria (Scientific)

Contact information

Type(s)
Scientific

Contact name
Dr Rohaida Zakaria

Contact details
Department of Obstetrics and Gynecology
University Malaya Medical Centre
Lembah Pantai
Kuala Lumpur
Malaysia
59100

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2017103-5623

Study information

Scientific Title
Induction of Labour with 16 F versus 22 F versus 28 F size Foley Catheter: A randomised trial

Study objectives

Induction of labour with larger size of Foley catheter in a woman with an unfavourable cervix will be easier to insert and will result in less insertion time. We believed less insertion time will cause less pain to participant and higher successful rate.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Research Ethics Committee University of Malaya Medical Centre, 25/10/2017, ref: MREC ID No: 2017103=5623

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Diagnostic

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
Induction of labour

Interventions
Randomisation is by the opening of sealed opaque and numbered envelope with lowest available envelope assigned in strict order. Randomization sequence is generated using a random number generator at Random.org in random block of 6 or 9 sequence, generated by investigator who is not involved in recruitment.

Participants are randomised into 3 arms; 16 F, 22 F and 28 F. Only specified investigator performs the intervention using standardised protocol in all group. Participants are placed in lithotomy position. The provider performs a vaginal examination under aseptic condition to identify the os. Insertion is by slitting the Foley catheter along the operator’s hand and fingers lubricated with water soluble lubricant into endocervical canal. Once the tip of the catheter is past the internal os, the catheter is filled with 60mL of sterile water and then retracted so that the balloon rested on the cervical os. The external end of the Foley catheter are taped without tension to the medial aspect of the women’s thigh.

In the event of a failed insertion a vaginal speculum method of insertion using the same catheter bore are attempted if the participant consents. This method involves inserting a sterile Cusco speculum lubricated with water soluble lubricant into the vagina to visualise the cervix followed

by a sponge forceps guided threading of Foley catheter into the cervical canal. Following successful insertion of Foley catheter, standard institutional care applicable to Foley catheter labour induction shall apply.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Catheter Insertion time (total minutes to successful catheter placement at first attempt)
2. Patient reported pain (VNRS 0 to 10, taken immediately after first attempt with successful insertion)
3. Patient pain score by Insertion failure rates (placement time more than 5 minutes, procedure abandon by provider or requested by participant during insertion, catheter unable to pass through cervical canal or inadvertent amniotomy)

Secondary outcome measures
Maternal outcomes:
1. Time of catheter expelled or evacuated
2. Maternal satisfaction with their care since allocation to the intervention until removal of catheter
3. Use of additional prostaglandin for cervical ripening
4. Use of oxytocin for intrapartum augmention
5. Use of regional analgesia in labour
6. Timing from intervention to delivery
7. Mode of delivery and indication/s of caesarean section
8. Estimated postdelivery blood loss
9. Fever (intrapartum and up to patient discharge)

Neonatal outcomes:
1. Apgar score at 1 and 5 minutes
2. Arterial cord pH
3. Birth weight
4. Neonatal admission

Overall study start date
01/07/2017

Completion date
31/12/2018

Eligibility

Key inclusion criteria
1. Women with unfavourable cervix undergoing cervical ripening and induction of labour at term in University Malaya Medical Centre, Kuala Lumpur
2. Scheduled induction of labour
3. Aged 18 years and above
4. Gestational age of > 37 weeks at enrolment
5. Unfavourable cervix (Bishop Score ≤ 5)
6. Reassuring pre induction fetal cardiotocography (CTG)
7. Cephalic presentation

8. Singleton pregnancy
9. Intact membranes

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
147

Total final enrolment
127

Key exclusion criteria
1. Allergic to latex
2. Inability to consent
3. Known gross fetal anomaly
4. Absolute contraindication to vaginal delivery

Date of first enrolment
15/12/2017

Date of final enrolment
15/12/2018

Locations

Countries of recruitment
Malaysia

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

Sponsor information

Organisation
University Malaya Medical Centre

Sponsor details
O&G Department
University Malaya Medical Centre
Lembah Pantai
Malaysia
59100

Sponsor type
University/education

ROR
https://ror.org/00vkrxq08

Funder(s)

Funder type
University/education

Funder Name
University of Malaya Medical Centre

Results and Publications

Publication and dissemination plan
Planned publication in a high impact peer reviewed journal. See additional files for study protocol.

Intention to publish date
31/12/2019

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. Rohaida Binti Zakaria
Email: rohaidazakaria@yahoo.com
Telephone no: +6017 3613076

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file		07/12/2017	02/04/2019	No	No
Results article		01/03/2022	27/10/2022	Yes	No