ISRCTN21224268 https://doi.org/10.1186/ISRCTN21224268

# 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
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Malaysia
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# 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 |