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**RESEARCH PROPOSAL FOR MASTER OF MEDICINE**

**(OBSTETRICS AND GYNAECOLOGY)**

**DEPARTMENT OF OBSTETRICS AND GYNAECOLOGY**

**UNIVERSITI MALAYA**

**TITLE**

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

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**TITLE**

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

**INTRODUCTION AND LITERATURE REVIEW**

Labour induc'on is the use of medica'ons or other methods to bring on (induce) labour in

an e<ort to have a vaginal birth.

1

 The American Congress of Obstetricians and Gynecologists

describe the Foley as an acceptable induc'on agent because it has demonstrated high

e>cacy and safety across several studies.

2

 WHO recommended balloon catheter as one of

the methods for induc'on of labour

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%&'(#()5\*+(%,9:.3$2;#2$\*3/02<,(&233()\*,';&.\*53'8%5\*'#=()/02%/2,%3/(

.#.'\*/2  5\*+(%,

Induction of labour is the process of using drugs or other methods to encourage labour to start artificially.[[1]](#endnote-1) It is the most commonly performed obstetric intervention.[[2]](#endnote-2) In the United Kingdom it occurs in 25% of pregnancies in 2013 to 2014.[[3]](#endnote-3) The American College of Obstetricians and Gynecologists describe the Foley as an acceptable induction agent because it has demonstrated high efficacy and safety across many studies.[[4]](#endnote-4) World Health Organization also recommends the use of a balloon catheter for induction of labour.[[5]](#endnote-5)

A Foley catheter is a self retaining flexible tube that is widely used to drain urine perurethrally and can also be used to ripen the [cervix](https://en.wikipedia.org/wiki/Cervix) during [induction of labour](https://en.wikipedia.org/wiki/Induction_of_labor). It is sized using French units (F). 1 F is equivalent to 0.33 mm diameter.[[6]](#endnote-6)

Foley catheter is in clinical use for induction of labour since 1967,[[7]](#endnote-7) but there is no guidelines recommendation on optimal size to be used.2,5

In a PubMed search done in July 2017, using the terms, Foley, induction of labour or labor, and randomized or randomised trials, we retrieved 120 publications. We identified 99 clinical trials and we were able to obtain 77 publications in full text. The range of catheter size described is from 14 F to 30 F with size 16 F and 18 F being the most often used. From the literature review, there are no trials comparing Foley catheter bore in labour induction. Although, the insertion failure rates reported across these studies are low (0 – 13%), studies typically permit multiple insertion attempts. In these 77 trial reports the ease of insertion and patient acceptability related to catheter size has not been studied. (The 77 trial publications are summarized in Table 1).

In our institution, Foley catheter placement is performed with size 14 F to 16 F as they are readily available. The exact size depends on provider preference. We believed that a larger bore catheter provides better rigidity navigating the cervical canal more easily.

Hence, we designed this randomised trial to evaluate, whether there is a difference in insertion time, patient pain score and failed insertion across 3 different Foley catheter sizes. We chose size 16 F (5.3 mm), 22 F (7.3 mm) and 28 F (9.3 mm) to evaluate evenly distributed size increment whilst keeping within the size range in literature and appreciating that size 16 F as most commonly used in literature.

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| No. | Author | Year | Country | Foley Size | n | f | Technique |
|  | Surita et al[[8]](#endnote-8) | 2004 | Brazil | 14F/ 30mL | 70 | 0 | Unspecified |
|  | Filho et al[[9]](#endnote-9) | 2010  | Brazil | 14F/ 30mL | 121 | 0 | Speculum |
|  | Nironmanesh et al[[10]](#endnote-10) | 2003  | Iran | 14F/ 30mL | 45 | 0 | Speculum |
|  | Sciscone et al [[11]](#endnote-11) | 1998 | U.S | 14F/ 30mL | 77 | 0 | Speculum |
|  | Gibson K.S et al[[12]](#endnote-12) | 2013 | U.S | 14F/ 30mL | 197 | 6 | Speculum |
|  |  |  |  |  |  |  |  |
|  | Aduloju et al[[13]](#endnote-13) | 2016 | New Zealand | 16F/ 30mL | 70 | 0 | Speculum /+ sponge forceps |
|  | Policiano et al[[14]](#endnote-14) | 2017 | Portugal | 16F/ 40mL | 201 | 0 | Speculum |
|  | Ning Gu et al[[15]](#endnote-15) | 2015 | China | 16F/ 30mL or 80mL | 504 | 2 | Speculum |
|  | Patabendige et al[[16]](#endnote-16) | 2017 | Sri Lanka | 16F/ 50mL | 56 | 0 | Unspecified |
|  | Pennell et al[[17]](#endnote-17) | 2009 | Australia | 16F/ 30mL | 109 | 1 | Unspecified |
|  | Henry et al[[18]](#endnote-18) | 2013 | Australia | 16F/ 30mL | 50 | 0 | Speculum |
|  | Ugwo et al[[19]](#endnote-19) | 2013 | Nigeria | 16F/ 30mL | 50 | 0 | Speculum |
|  | Manish et al[[20]](#endnote-20) | 2016 | India | 16F/ 30mL or 80mL | 77 | 0 | Speculum |
|  | Sciscione et al[[21]](#endnote-21) | 2003 | Newark | 16F/ 30mL | 63 | 0 | Unspecified |
|  | Chung et al[[22]](#endnote-22) | 2003 | US | 16F/ 30mL | 54 | 4 | Speculum |
|  | Amorosa et al[[23]](#endnote-23) | 2017 | Newland | 16F/ 30mL | 62 | 0 | Speculum & sponge forceps/ Digital |
|  | Ziyaudin et al[[24]](#endnote-24) | 2013 | India | 16F/30mL | 35 | 0 | Unspecified |
|  | Dahiya K et al[[25]](#endnote-25) | 2012 | India | 16F/50mL | 50 | 0 | Unspecified |
|  | Abramovici et al[[26]](#endnote-26) | 1999 | US | 16F/ 30mL | 77 | 0 | Speculum |
|  | James et al[[27]](#endnote-27) | 1994 | India | 16F/ 30mL  | 187 | 0 | Unspecified |
|  | Chavakula et al[[28]](#endnote-28) | 2015 | India | 16F/ 30mL | 54 | 0 | Speculum |
|  | Dalui et al[[29]](#endnote-29) | 2003 | India | 16F/ 30mL | 50 | 0 | Speculum & sponge forceps |
|  | Connolly et al[[30]](#endnote-30) | 2017 | US | 16F/ 60mL | 141 | 0 | Unspecified |
|  | Edward et al[[31]](#endnote-31) | 2014 | US | 16F/ 30mL | 185 | 0 | Unspecified |
|  | El-Khayat et al[[32]](#endnote-32) | 2014 | Egypt | 16F/ 60mL | 200 | 0 | Speculum |
|  | M. Kashanian[[33]](#endnote-33) | 2005 | Iran  | 16F/ Unspecified | 100 | 0 | Unspecified |
|  | Ducarme et al[[34]](#endnote-34) | 2015 | France | 16F/30mL | 255 | 0 | Unspecified |
|  | Mei-Dan et al[[35]](#endnote-35) | 2011 | US | 16F/ 30mL | 88 | 1 | Speculum & sponge forceps |
|  | Tabowei et al[[36]](#endnote-36) | 2003 | Nigeria | 16F/50mL | 61 | 0 | Unspecified |
|  | Adeniji et al[[37]](#endnote-37) | 2005 | Nigeria | 16F/ 50mL | 96 | 0 | Speculum & sponge forceps |
|  |  |  |  |  |  |  |  |
|  | Ahmed et al[[38]](#endnote-38) | 2016 | Egypt | 18F/ 50mL | 39 | 2 | Speculum |
|  | Cromi et al[[39]](#endnote-39) | 2006 | Italy | 18F/ 50mL | 607 | 5 | Speculum |
|  | Shuchita et al[[40]](#endnote-40) | 2017 | US | 18F/ 30mL | 602 | 4 | Speculum or Digital |
|  | Cromi et al[[41]](#endnote-41) | 2010 | Italy | 18F/ 50mL | 131 | 1 | Speculum |
|  | El Khouly[[42]](#endnote-42) | 2016 | Egypt | 18F/ 30mL | 72 | 0 | Speculum & sponge forceps |
|  | Gonsalves et al[[43]](#endnote-43) | 2016 | Oman | 18F/ 30mL to 60mL | 68 | 0 | Unspecified |
|  | Levine et al[[44]](#endnote-44) | 2016 | US | 18F/ 30mL | 248 | 9 | Speculum or Digital |
|  | Jonsson et al[[45]](#endnote-45) | 2011 | Sweden | 18F/ 50mL | 42 | 0 | Speculum or Digital |
|  | Bujold et al[[46]](#endnote-46) | 2004 | US | 18F/ 50mL | 255 | 0 | Unspecified |
|  | Culver et al[[47]](#endnote-47) | 2004 | US | 18F/ 30mL | 83 | 0 | Unspecified |
|  | Mullin et al[[48]](#endnote-48) | 2002 | US | 18F/ 60mL | 100 | 0 | Unspecified |
|  | Thomas et al[[49]](#endnote-49) | 1986 | UK | 18F/ 30mL | 32 | 0 | Speculum & sponge forceps |
|  | Owalabi et al[[50]](#endnote-50) | 2005 | Nigeria | 18F/ 30mL | 60 | 0 | Speculum |
|  | Liu et al[[51]](#endnote-51) | 1998 | Taiwan | 18F/ 30mL | 32 | 4 | Unspecified |
|  | Onge et al[[52]](#endnote-52) | 1994 | Canada | 18F/ 30mL | 36 | 0 | Speculum |
|  | Delaney et al[[53]](#endnote-53) | 2014 | US | 18F/ 30mL or 60mL | 195 | 0 | Unspecified |
|  | Fitzpatrick et al[[54]](#endnote-54) | 2012 | US | 18F/ 30mL | 136 | 19 | Speculum |
|  | Afolabi et al[[55]](#endnote-55) | 2005 | Nigeria | 18F/ 30mL | 50 | 0 | Unspecified |
|  | Gelisen et al[[56]](#endnote-56) | 2004 | Turkey | 18F/ 50mL | 100 | 8 | Unspecified |
|  | M. Kandil et al[[57]](#endnote-57) | 2012 | Egypt | 18F/ 30mL | 50 | 0 | Speculum&2sponge forceps |
|  | Fatemeh et al[[58]](#endnote-58) | 2012 | Iran | 18F/ 50mL | 59 | 0 | Unspecified |
|  | Sharma et al[[59]](#endnote-59) | 2014 | US | 18F/ 30mL | 80 | 5 | Speculum |
|  | Al-Taani MI[[60]](#endnote-60) | 2004 | Iran | 18F/ 50mL | 72 | 0 | Speculum |
|  |  |  |  |  |  |  |  |
|  | Pettker et al[[61]](#endnote-61) | 2008 | US | 20F/ 30mL | 200 | 0 | Speculum/sponge forceps |
|  |  |  |  |  |  |  |  |
|  | Mizrachi et al[[62]](#endnote-62) | 2016 | Berlin | 22F/ 80mL | 173 | 0 | Speculum |
|  | Forgie et al[[63]](#endnote-63) | 2015 | US | 22F/ 50mL | 123 | 16 | Digital |
|  | Kruit et al[[64]](#endnote-64) | 2015 | Finland | 22F/ 30mL to 60mL | 432 | 0 | Unspecified |
|  | Moini et al[[65]](#endnote-65) | 2003 | Iran | 22F/ 30mL | 35 | 0 | Unspecified |
|  | Kruit et al[[66]](#endnote-66) | 2017 | Finland | 22F/ 50mL | 361 | 0 | Unspecified |
|  | Ghanaie et al[[67]](#endnote-67) | 2013 | Iran | 22F/ 30mL | 240 | 2 | Unspecified |
|  | Guinn et al[[68]](#endnote-68) | 2003 | US | 22F/ 30mL | 100 | 13 | Speculum if failed - Speculum & sponge forceps |
|  |  |  |  |  |  |  |  |
|  | Perry K. G et al[[69]](#endnote-69) | 1997 | US | 24F/ 50mL | 65 | 0 | Unspecified |
|  | Hemlin et al[[70]](#endnote-70) | 1998 | Sweden | 24F/ 30mL | 43 | 0 | Unspecified |
|  | Barrilleaux et al[[71]](#endnote-71) | 2002 | US | 24F/ 50mL | 223 | 0 | Speculum |
|  | Hill et al[[72]](#endnote-72) | 2009 | US | 24F/ 50mL | 114 | 4 | Speculum |
|  | Kashanian et al[[73]](#endnote-73) | 2008 | Iran | 24F/ 30mL or 80mL | 180 | 0 | Unspecified |
|  |  |  |  |  |  |  |  |
|  | Maslovitz et al[[74]](#endnote-74) | 2009 | Israel | 26F/ 50mL | 1083 | 19 | Speculum |
|  | Barkai et al[[75]](#endnote-75) | 1997 | Israel | 26F/ 30mL | 48 | 0 | Speculum |
|  |  |  |  |  |  |  |  |
|  | Karjane et al[[76]](#endnote-76) | 2006 | US | 30F/ 50mL | 142 | 3 | Speculum if failed - digital |
|  |  |  |  |  |  |  |  |
|  | Jozwiak et al[[77]](#endnote-77) | 2011 | Netherland | 16-18F/ 30mL | 412 | 13 | Speculum |
|  | Eikelder et al[[78]](#endnote-78) | 2016 | Netherland | 16-18F/ 30mL | 921 | 49 | Speculum or digital |
|  | Husain et al[[79]](#endnote-79) | 2016 | Pakistan | 16-18F/ 30mL | 169 | 5 | Speculum or digital |
|  |  |  |  |  |  |  |  |
|  | Roni Levy[[80]](#endnote-80) | 2003 | Israel | \*30mL or 80mL | 205 | 0 | Speculum |
|  | Sanberg et al[[81]](#endnote-81) | 2017 | Netherland | \*30mL or 80mL | 174 | 0 | Unspecified |
|  | Levy et aL[[82]](#endnote-82) | 2002 | Israel | \*60mL | 211 | 0 | Speculum |
|  | Carbone et al[[83]](#endnote-83) | 2013 | US | \*60mL | 59 | 0 | Speculum or digital |
|  | Onah H.E[[84]](#endnote-84) | 2002 | Nigeria | \*30mL | 30 | 0 | Unspecified |
| \*size of Foley was unspecifiedn participantf failed insertion |
| TABLE 1 |

|  |  |  |
| --- | --- | --- |
| No. | Foley Size (F) | Total Publications |
|  | 14 | 5 |
|  | 16 | 25 |
|  | 18 | 24 |
|  | 20 | 1 |
|  | 22 | 7 |
|  | 24 | 5 |
|  | 26 | 1 |
|  | 30 | 1 |
|  | 16 or 18 | 3 |
|  | Unspecified | 5 |
|  | Total | 76 |
| TABLE 2 |

**OBJECTIVE OF STUDY**

The purpose of this study is to find a catheter bore with the best insertion outcome when used for labour induction using 16 F (5.3 mm) versus 22 F (7.3 mm) versus 28 F (9.3 mm) in a woman with an unfavourable cervix at term by comparing the :

1. Catheter Insertion time (first attempt).
2. Patient reported pain
3. Insertion failure rate.

**RESEARCH HYPOTHESIS**

Induction of labour with a larger size of Foley catheter in a woman with an unfavourable cervix will be easier to insert and takes less time hence reduces insertion pain.

**ENDPOINTS**

Primary endpoint

1. Catheter Insertion time (successful catheter placement at first attempt; a failed attempt is scored as 10 minutes by design).
2. Insertion related pain score (VNRS 0 to 10, taken immediately after first attempt with successful insertion; a failed attempt is scored 10 by design).
3. Insertion failure at first attempt (defined as 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 endpoint

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

**METHODOLOGY**

Study design

Randomised trial

Population of Study

Women with unfavourable cervix undergoing cervical ripening and induction of labour at term in University Malaya Medical Centre, Kuala Lumpur

Inclusion criteria

Scheduled induction of labour

Aged 18 years and above

Gestational age of > 37 weeks at enrolment

Unfavourable cervix (Bishop Score ≤ 5, 13 point score)

Reassuring pre induction fetal cardiotocography (CTG)

Cephalic presentation

Singleton pregnancy

Intact membranes

Exclusion criteria

Allergic to latex

Inability to consent

Known gross fetal anomaly

Absolute contraindication to vaginal delivery

**METHODS**

The decision to proceed with induction of labour with Foley catheter will be made by usual care provider.

All women for induction of labour will be assessed for eligibility and will be counseled regarding this study. Patient information sheet will be given and if the women agreed to participate, informed consent will be obtained. After obtaining informed consent, the care team involved in the patient care will be notified of the patient’s participation in the study.

Pre induction fetal cardiotocography (CTG) and assessment of Bishop Score will be done as routine. If the CTG and Bishop Score are not suitable, participants will be excluded from the study.

Randomisation will be blocks of 6 or 9 generated using a random number generator (random.org) by a researcher not involved in recruitment. The random allocation sequence will be placed in sealed numbered opaque envelopes for strict number order assignment to participants. Opened unused envelopes will be discarded and the reason recorded.

Random assignment to Foley catheter size 16 F or 22 F or 28 F will be achieved by opening the lowest remaining numbered sealed envelope.

Blinding of care provider and participant is deemed impractical due to the nature of the intervention.

Women will be positioned in the dorsal lithotomy position in the bed. Insertion technique for all 3 sizes of Foley catheter (16, 22 or 28F) will be started in same way. The provider will perform 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 was past the internal os, the catheter will be 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 will be taped without tension to the medial aspect of the women’s thigh.

Using a stopwatch operated by research assistant, insertion time begins when the operator’s finger entered the vagina and ended with confirmation of success on retention of the inflated balloon after retraction testing. Procedure related pain is scored at the end of the successful attempt with a visual numerical score (VNRS 0 to 10). An unsuccessful attempt is scored 10 by design.

Post insertion care will follow the institutional and care provider standard practice for labour induction with a transcervical balloon device. If not already expelled, the Foley catheter is usually removed after about 12 hours and a reassessment carried out on the next appropriate step in the labour induction.

Failure of insertion (first attempt) is defined as:

1. placement time more than 5 minutes
2. procedure abandon by provider or requested by participant during insertion,
3. catheter unable to pass through cervical canal, or
4. Inadvertent amniotomy.

If inadvertent amniotomy occurs, patient will be advised to proceed with medical methods (e.g. prostaglandins or oxytocin infusion). If the first insertion attempt fails, a vaginal speculum method of insertion using the same catheter bore will be 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. If the participant decided against further Foley catheter insertion, medical methods will be used,

Data will be collected as per case report form.

**STUDY PROTOCOL FLOW CHART**

Assess for eligibility with eligibility & recruitment form

Counsel, patient information sheet will be given and obtain informed consent

CTG and Bishop score

Exclude

- Bishop score > 5

- Non reassuring CTG

Randomized in 3 groups

Insertion of Foley catheter size 28 F

Insertion of Foley catheter size 22 F

Insertion of Foley catheter size 16 F

Primary outcome measures

* If inadvertent amniotomy counseled for medical methods.
* If the placement > 5 minutes or
* abandon by provider or
* participant refused or
* unable to pass through the cervical canal

counseled for IOL with the same bore of catheter using a sterile Cusco speculum or medical methods.

CTG post insertion and at least 6 hourly

Spontaneous expulsion or catheter removal after 12 hours

Continuation of care as per UMMC protocol

Secondary outcome measures

****

Study Number

**CASE REPORT FORM**

Patient’s Sticker

Date of recruitment : \_\_ / \_\_ / \_\_ (dd/ mm/ yy)

Date : \_\_ / \_\_ / \_\_ (dd/ mm/ yy)

EDD : \_\_ / \_\_ / \_\_ (dd/ mm/ yy)

**Patient characteristics**

Age : \_\_\_\_\_

Gravida : \_\_\_\_\_ Para : \_\_\_\_\_ Abortion : \_\_\_\_\_\_

Gestational age : \_\_\_\_\_\_\_\_\_\_

Latest recorded weight : \_\_\_\_\_\_\_\_ kg

Height : \_\_\_\_\_\_\_\_\_ cm

Occupation :

* Employed
* Self employed
* Student
* Housewife
* Other : \_\_\_\_\_\_\_\_\_\_\_

Education level :

* Up to primary
* Secondary
* Diploma
* Degree
* Masters
* PhD

Ethnicity :

* Malay
* Chinese
* Indian
* Other : \_\_\_\_\_\_\_\_\_\_\_

Indication/s for IOL : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Previous LSCS :

* Yes : Year : \_\_\_\_\_ indication : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* No

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Score | 0 | 1 | 2 | 3 |
| Dilation | Closed | 1-2 cm | 3-4 cm | ≥ 5 cm |
| Length |  > 4 cm | 3-4 cm | 1-2 cm | O cm |
| Consistency | Firm | Medium | Soft |  |
| Position | Posterior | Mid | Anterior |  |
| Station |  ≤-3 cm | -2 cm | -1,-0 cm | ≥ 1 cm |

Bishop score :

Pre induction Bishop Score : \_\_\_\_\_\_\_\_\_\_\_\_\_

Intervention performed by : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Primary Outcome**

1. Time of insertion

Date : \_\_ / \_\_ / \_\_ (dd/ mm/ yy)

Time of insertion : \_\_\_:\_\_\_(hr:min)

Stop clock start : \_\_\_:\_\_\_(min: sec) Stop clock completed : \_\_\_:\_\_\_(min: sec)

Total time : \_\_\_:\_\_\_(min: sec)

1. Pain score

Patient pain score after first attempt of Foley catheter insertion.

**What is your pain score during the insertion of the catheter?**

**Please circle the score below :**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

Worst pain imaginable



No pain



1. Insertion failure rates

Successful?

* Yes
* No :
	+ - * Abandon by provider
			* Abandon by participant
			* Catheter unable to pass through cervical canal
			* Inadvertent Amniotomy

Second method :

* Speculum : Yes No
* Size of Foley catheter : \_\_\_\_\_ F
* Medical induction : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Maternal outcome**

1. Time of catheter expelled or removed : \_\_ / \_\_ / \_\_ (dd/ mm/ yy)

 : \_\_\_:\_\_\_\_ (hr:min)

1. Maternal satisfaction with their care since allocation to the intervention until removal of catheter.

**What is your satisfaction score since insertion of the catheter until the removal of the catheter? Please circle the score below :**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

Very dissatisfied



Very dissatisfied



1. Use of additional prostaglandin for cervical ripening?
* Yes Please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* No
1. Use of oxytocin for intrapartum augmention?
* Yes
* No
1. Use of regional analgesia in labour?
* Yes Please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* No
1. Time of delivery : Date \_\_\_/ \_\_\_/ \_\_\_ (dd/mm/yy)

 Time: \_\_\_:\_\_\_ (hr:min)

1. Mode of Delivery:
* SVD
* Caesarean section. Indication/s: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* Instrumental delivery: Forceps / Vacuum. Indication/s: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
1. Estimated blood loss postdelivery: \_\_\_\_\_\_\_\_\_\_ ml
2. Temperature: Intrapartum \_\_\_\_\_\_ 0C postnatal up to discharge \_\_\_\_\_\_ 0C

**Neonatal Outcome**

1. Apgar Score : \_\_\_\_\_\_ 1 mins / \_\_\_\_\_\_ 5 mins
2. Arterial Cord pH : \_\_\_\_\_\_\_
3. Birth weight : \_\_\_\_\_\_\_\_\_\_ kg
4. Required neonatal admission :
* Yes : Place of admission : PNW / SCN / NICU / Others

Reason for admission : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

* No

**STUDY FLOW CHART**

Eligibility

Women for induction of labour at term and fulfil the inclusion criteria

Exclusion criteria

- Allergic to latex

Randomized in 3 groups

Foley catheter size 22 F

Cervical ripening and delivery

the inclusion criteria

Foley catheter size 16 F

Cervical ripening and delivery

Foley catheter size 28 F

Cervical ripening and delivery

the inclusion criteria

Data collection

Statistical analysis

Completion thesis writing

Thesis submission

**ETHICAL CONSIDERATION**

This study is submitted to the UMMC Medical Research and Ethics committee, the local institutional review board for approval. Patient will be given an information sheet, have their oral queries addressed and written informed consent obtained to participate in the study.

**SAMPLE SIZE CALCULATION**

For the primary outcome of time taken for successful insertion, taking a mean ± standard deviation catheter insertion time of 2 minutes ± 1.35 minutes (based on Forgie et al), assuming a 1 minute difference in insertion time between compared arms, taking alpha of 0.017 (Bonferroni correction given 3 arm design with 3 one to one comparisons), 80% power, one to one ratio, applying the Student t test, 39 participants are required in each arm.

For the primary outcome of insertion pain score using 0-10 VNRS, a taking a mean ± standard deviation 4.43 ± 1.24 (based on Fogie et al), assuming a 1 point difference between compared arms, taking alpha of 0.017 (Bonferroni correction given 3 arm design with 3 one to one comparisons), 80% power, one to one ratio, applying the Student t test, 33 participants are required in each arm.

For the primary outcome of successful insertion, assuming 90% vs 60% rate between the compared arms, taking alpha of 0.017 (Bonferroni correction given 3 arm design with 3 one to one comparisons), 80% power, one to one ratio, applying the Chi Square test, 42 participants are required in each arm.

Calculated using online calculator by Dupont WD, Plummer WD: 'Power and Sample Size Calculations: A Review and Computer Program', Controlled Clinical Trials 1990; 11:116-28.

**STATISTICAL ANALYSIS**

Data will be entered into SPSS statistical software. Normally distributed continuous data will be analyzed with Student’s t test. Chi square test will be used for categorical or nominal data and Mann-Whitney U test on non-normally distributed or ordinal data. Primary comparisons will be trial arm to arm on a one to one basis and Bonferroni correction made to take into account the 3-arm design.

**STUDY DURATION**

The delivery rate in University Malaya Medical centre is about 5000 per year. Induction of labour rate approximately is about 20% per year.

Assuming that 30% (based on survey) of women will agreed for induction of labour with mechanical method, then 1000 x 0.3 = 300 women might be recruited per year.

We plan to recruit 126 women into this study which should take about 6 months (126/300 x 12 = 5.04)

This study will be conducted from as soon as possible as approved by Ethical Committee Board and should run for 6 months barring unexpected events.

**GANNT CHART**

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| --- | --- | --- | --- | --- | --- | --- |
| **Duration** | **June – July 2017** | **July – Sept 2017** | **Sept – Nov 2017** | **Dec 2017 – Dec 2018**  | **Jan 2019** | **Feb 2019** |
| **Literature review** | ✓ |   |   |   |   |   |
| **Proposal preparation****& presentation** | ✓ | ✓ |   |   |   |   |
| **Ethics review** |   |  | ✓ |  ✓ |   |   |
| **Data collection** |   |   |   | ✓ |  ✓ |   |
| **Data analysis and writing** |   |   |   |   | ✓ |  ✓ |
| **Thesis submission** |   |   |   |   |   | ✓ |

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