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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 unspecified  n participant  f 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**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **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** |  |  |  |  |  | ✓ |

REFERENCES

1. http://nationalwomenshealth.adhb.govt.nz/services/maternity/pregnancy-advice/induction-of-labour [↑](#endnote-ref-1)
2. National Institute for Health and Clinical Excellence. Insertion of a double balloon catheter for induction of labour in pregnant women without previous caesarean section. Interventional procedures guidance [IPG528] Published date: July 2015  [↑](#endnote-ref-2)
3. https://www.nct.org.uk/professional/research/maternity%20statistics/maternity-statistics-england [↑](#endnote-ref-3)
4. American College of Obstetrician and Gynaecologist. Induction of labor. ACOG Practice bulletin no.107. Obstet Gynecol 2009;114;386-97. [↑](#endnote-ref-4)
5. World Health Organization. WHO recommendations for induction of labour. Geneva: WHO; 2011. Available from: http://whqlibdoc.who.int/publications/2011/9789241501156\_eng.pdf. [↑](#endnote-ref-5)
6. Foley catheter. <https://en.wikipedia.org/wiki/Foley_catheter>. Accessed on 9th July 2017. [↑](#endnote-ref-6)
7. Embrey MP, Mollison BG. The unfavorable cervix and induction of labor using cervical balloon. J Obstet Gynaecol Br Common 1967;74:44-5. [↑](#endnote-ref-7)
8. Surita FG, Cecatti JG, Parpinelli MA, Krupa F, Pinto E Silva JL. [Hyaluronidase](https://www.ncbi.nlm.nih.gov/pubmedhealth/PMHT0010577) versus Foley [catheter](https://www.ncbi.nlm.nih.gov/pubmedhealth/PMHT0022169) for cervical ripening in high-risk term and post term [pregnancies](https://www.ncbi.nlm.nih.gov/pubmedhealth/PMHT0023077). Int J Gynaecol Obstet 2005;88:258–64. [↑](#endnote-ref-8)
9. Filho OB, Albuquerque RM, Cecatti JG. A randomized controlled trial comparing vaginal misoprostol versus Foley catheter plus oxytocin for labor induction. Acta Obstet Gynecol Scand 2010;89:1045–52. [↑](#endnote-ref-9)
10. Niromanesh S, Mosavi-Jarrahi A, Samkhaniani F. Intracervical Foley catheter balloon vs. prostaglandin in preinduction cervical ripening. Int J Gynaecol Obstet 2003;81:23–7. [↑](#endnote-ref-10)
11. Sciscione AC, McCullough H, Manley JS, Shlossman PA, Pollock M, Colmorgen GH. A prospective, randomized comparison of Foley catheter insertion versus intracervical prostaglandin E2 gel for preinduction cervical ripening. Am J Obstet Gynecol 1999;180:55–60. [↑](#endnote-ref-11)
12. **Gibson KS, Mercer BM, Louis JM. Inner thigh taping vs traction for cervical ripening with a Foley catheter: a randomized controlled trial. Am J Obstet Gynecol 2013;209:272.e1-7.** [↑](#endnote-ref-12)
13. Aduloju OP, Akintayo AA, Adanikin AI et al. Combined Foley’s catheter with vaginal misoprostol for pre-induction cervical ripening: A randomised controlled trial. Aust N Z J Obstet Gynaecol. 2016; [↑](#endnote-ref-13)
14. Catarina Policiano, Mariana Pimenta, Diana Martins, Nuno Clode. Efficacy and safety of Foley Catheter Ballon for Cervix Priming in Term Pregnancy. Acta Med Port 2017 Apr;30(4):281-284 [↑](#endnote-ref-14)
15. Ning Gu, Tong Ru, Zhiqun Wang, Yimin Dai, Mingming Zheng, Biyun Xu, Yali Hu. Foley Catheter for Induction of Labor at Term. An Open-Label, Randomized Controlled Trial. PLos ONE 10(8):e0136856. [↑](#endnote-ref-15)
16. Patabendige M, Jayawardane. Foley catheter for cervical priming in induction of labour at University Obstetrics Unit, Colombo, Sri Lanka: a clinical audit with a patient satisfaction survey. BMC nRes Notes (2017) 10:155 [↑](#endnote-ref-16)
17. Pennell CE, Henderson JJ, O’Neill MJ, McCleery S, Doherty DA, Dickinson JE. Induction of labour in nulliparous women with an unfavourable cervix: a randomised controlled trial comparing double and single balloon catheters and PGE2 gel. BJOG. 2009; 116: 1443-1452. [↑](#endnote-ref-17)
18. Henry A, Madan A, Reid R, Tracy S, Austin K, Welsh A, et al Outpatient Foley catheter versus inpatient prostaglandin E2 gel for induction of labour: a randomised trial. BMC Pregnancy Childbirth 2013; **13** 25 [↑](#endnote-ref-18)
19. Ugwu EO, Onah HE, Obi SN, Dim CC, Okezie OA, Chigbu CO, et al. Effect of the Foley catheter and synchronous low dose misoprostol administration on cervical ripening: a randomised controlled trial. J Obstet Gynaecol 2013;33(6):572–7. [↑](#endnote-ref-19)
20. # [Anuja Abraham](http://journals.sagepub.com/author/Abraham%2C+Anuja), [Vishali Jeyaseelan](http://journals.sagepub.com/author/Jeyaseelan%2C+Vishali), [Jiji E Mathews](http://journals.sagepub.com/author/Mathews%2C+Jiji+E). A randomised controlled trial comparing 30 mL and 80 mL in Foley catheter for induction of labour after previous Caesarean section. Sage Journal. Volume: 46 issue: 4, page(s): 205-211

    [↑](#endnote-ref-20)
21. Sciscione AC, Nguyen L, Manley J, Pollock M, Maas B, Colmorgen G. A randomized comparison of transcervical Foley catheter to intravaginal misoprostol for preinduction cervical ripening. Obstet Gynecol 2001;97(4):603–7. [↑](#endnote-ref-21)
22. Chung JH, Huang WH, Rumney PJ, Garite TJ, Nageotte MP. A prospective randomized controlled trial that compared misoprostol, Foley catheter, and combination misoprostol-Foley catheter for labor induction. Am J Obstet Gynecol 2003;189(4): 1031–5. [↑](#endnote-ref-22)
23. Amorosa JMH, Stone J, Factor SH, Booker W, Newland M, Bianco A. [A randomized trial of Foley Bulb for Labor Induction in Premature Rupture of Membranes in Nulliparas (FLIP).](https://www.ncbi.nlm.nih.gov/pubmed/28479288) Am J Obstet Gynecol. 2017 May 4. pii: S0002-9378(17)30568-9. doi: 10.1016/j.ajog.2017.04.038 [↑](#endnote-ref-23)
24. # Ziyauddin F, Hakim S, Beriwal S. The Transcervical Foley Catheter Versus the Vaginal Prostaglandin E2 Gel in the Induction of Labour in a Previous One Caesarean Section – A Clinical Study. [J Clin Diagn Res](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3576770/). 2013 Jan; 7(1): 140–143.

    [↑](#endnote-ref-24)
25. Krishna Dahiya, Kanika Malik, Archit Dahiya, Smiti Nanda. Comparison of the Efficacy of Foley Catheter Balloon with Dinoprostone Gel for Cervical Ripening at Term. International Journal of Clinical Medicine, 2012, 3, 527-531 [↑](#endnote-ref-25)
26. Abramovici D, Goldwasser S, Mabie BC, Mercer BM, Goldwasser R, Sibai BM: A randomized comparison of oral misoprostol versus Foley catheter and oxytocin for induction of labor at term. Am J Obstet Gynecol. 1999, 181: 1108-1112. 10.1016/S0002-9378(99)70090-6. [↑](#endnote-ref-26)
27. C. James, A. Peedicayil, L. seshadri. Use of Foley catheter as cervical ripening agent prior to induction of labour. International Journal of gynaecology & Obstetrics 57(1994)229-232. [↑](#endnote-ref-27)
28. # [Chavakula PR](https://www.ncbi.nlm.nih.gov/pubmed/?term=Chavakula%20PR%5BAuthor%5D&cauthor=true&cauthor_uid=25661322), [Benjamin SJ](https://www.ncbi.nlm.nih.gov/pubmed/?term=Benjamin%20SJ%5BAuthor%5D&cauthor=true&cauthor_uid=25661322), [Abraham A](https://www.ncbi.nlm.nih.gov/pubmed/?term=Abraham%20A%5BAuthor%5D&cauthor=true&cauthor_uid=25661322), [Londhe V](https://www.ncbi.nlm.nih.gov/pubmed/?term=Londhe%20V%5BAuthor%5D&cauthor=true&cauthor_uid=25661322), [Jeyaseelan V](https://www.ncbi.nlm.nih.gov/pubmed/?term=Jeyaseelan%20V%5BAuthor%5D&cauthor=true&cauthor_uid=25661322), [Mathews JE](https://www.ncbi.nlm.nih.gov/pubmed/?term=Mathews%20JE%5BAuthor%5D&cauthor=true&cauthor_uid=25661322). Misoprostol versus Foley catheter insertion for induction of labor in pregnancies affected by fetal growth restriction. [Int J Gynaecol Obstet.](https://www.ncbi.nlm.nih.gov/pubmed/?term=chavakula+foley) 2015 May;129(2):152-5.

    [↑](#endnote-ref-28)
29. Dalui R, Suri V, Ray P, Gupta I. Comparison of extraamniotic Foley Catheter and intracervical prostaglandin E gel for preinduction cervical ripening. Acta Obstet Gynaecol Scand 2005;84:362-7 [↑](#endnote-ref-29)
30. Connolly KA, Kohari KS, Rekawek P, Smilen BS, Miller MR, Moshier E, Factor SH, Stone JL, Bianco AT. [A randomized trial of Foley balloon induction of labor trial in nulliparas (FIAT-N).](https://www.ncbi.nlm.nih.gov/pubmed/27018464) Am J Obstet Gynecol. 2016 Sep;215(3):392.e1-6. doi: 10.1016/j.ajog.2016.03.034. Epub 2016 Mar 24. [↑](#endnote-ref-30)
31. Edwards RK, Szychowski JM, Berger JL, Petersen M, Ingersoll M, Bodea-Braescu AV, Lin MG. [Foley catheter compared with the controlled-release dinoprostone insert: a randomized controlled trial.](https://www.ncbi.nlm.nih.gov/pubmed/24807327) Obstet Gynecol. 2014 Jun;123(6):1280-7 [↑](#endnote-ref-31)
32. El-Khayat W, Alelaiw H, El-kateb A, Elsemary A. [Comparing vaginal misoprostol versus Foley catheter plus vaginal isosorbide mononitrate for labor induction.](https://www.ncbi.nlm.nih.gov/pubmed/25694257) J Matern Fetal Neonatal Med. 2016;29(3):487-92. [↑](#endnote-ref-32)
33. Kashanian M, Akbarian AR, Fekrat M. Cervical ripening and induction of labor with intravaginal misoprostol and Foley catheter cervical traction. Int J Gynecol Obstet 2006;92(1):79–80. [↑](#endnote-ref-33)
34. G. Ducarme, J. Grange, M. vital. Expansion dilatation balloons for cervical ripening in obstetric practice. Journal de Gynaecologist Obste (2016) 45, 112-119. [↑](#endnote-ref-34)
35. Mei-Dan E, Walfisch A, Suarez-Easton S, Hallak M. [Comparison of two mechanical devices for cervical ripening: a prospective quasi-randomized trial](https://www.ncbi.nlm.nih.gov/pubmed/21806490). J Matern Fetal Neonatal Med. 2012 Jun;25(6):723-7. [↑](#endnote-ref-35)
36. Tabowei TO, Oboro VO. Low dose intravaginal misoprostol versus intracervical balloon catheter for pre-induction cervical ripening. East Afr Med J 2003;80:91-4 [↑](#endnote-ref-36)
37. Adeniji OA, Oladokun A, Olayemi O, Adeniji OI, Odukogbe AA, Ogunbode O, et al. Pre-induction cervical ripening: transcervical foley catheter versus intravaginal misoprostol. J Obstet Gynaecol 2005;25(2):134–9. [↑](#endnote-ref-37)
38. Sayed Ahmed, W. A., Ibrahim, Z. M., Ashor, O. E., Mohamed, M. L., Ahmed, M. R., and Elshahat, A. M. (2016) Use of the Foley catheter versus a double balloon cervical ripening catheter in pre-induction cervical ripening in postdate primigravidae. J. Obstet. Gynaecol. Res., 42: 1489–1494. doi: [10.1111/jog.13086](http://dx.doi.org/10.1111/jog.13086). [↑](#endnote-ref-38)
39. Cromi A, Ghezzi F, Tomera S, Ucella S, Lischetti B, Bolis P.F. Cervical ripening with the Foley catheter. International Journal of Gynaecology and Obstetrics (2007)97,105-109. [↑](#endnote-ref-39)
40. Shuchita Mundle, Hillary Bracken, Vaishali Khedikar, Jayashree Mulik, Brian Faragher, Thomas Easterling, Simon Leigh, Paul Granby, Alan Haycox, Mark A Turner, Zarko Alfirevic, Beverly Winikoff, Andrew D Weeks. **Foley catheterisation versus oral misoprostol for induction of labour in hypertensive women in India (INFORM): a multicentre, open-label, randomised controlled trial**. The Lancet, 2017 [↑](#endnote-ref-40)
41. Cromi A, Ghezzi F, Agosti M, Serati M, Uccella S, Arlant V, et al. Is transcervical Foley [catheter](https://www.ncbi.nlm.nih.gov/pubmedhealth/PMHT0022169) actually slower than prostaglandins in ripening the [cervix](https://www.ncbi.nlm.nih.gov/pubmedhealth/PMHT0021895)? A [randomized study](https://www.ncbi.nlm.nih.gov/pubmedhealth/PMHT0025811). Am J Obstet Gynecol 2011;204:338.e1–7. [↑](#endnote-ref-41)
42. # [El Khouly NI](https://www.ncbi.nlm.nih.gov/pubmed/?term=El%20Khouly%20NI%5BAuthor%5D&cauthor=true&cauthor_uid=27922285). A prospective randomized trial comparing Foley catheter, oxytocin, and combination Foley catheter-oxytocin for labour induction with unfavourable cervix. [J Obstet Gynaecol.](https://www.ncbi.nlm.nih.gov/pubmed/?term=el-khouly+foley) 2017 Apr;37(3):309-314. doi: 10.1080/01443615.2016.1239075

    [↑](#endnote-ref-42)
43. Gonsalves H, Al-Riyami N, Al-Dughaishi T, Gowri V, Al-Azri M, Salahuddin A. Use of Intracervical Foley Catheter for Induction of Labour in Cases of Previous Caesarean Section: Experience of a single tertiary centre in Oman. Sultan Qaboos University Medical Journal. 2016;16(4):e445-e450. doi:10.18295/squmj.2016.16.04.007. [↑](#endnote-ref-43)
44. Levine LD, Downes KL, Elovitz MA, Parry S, Sammel MD, Srinivas SK. [Mechanical and Pharmacologic Methods of Labor Induction: A Randomized Controlled Trial.](https://www.ncbi.nlm.nih.gov/pubmed/27824758) Obstet Gynecol. 2016 Dec;128(6):1357-1364. [↑](#endnote-ref-44)
45. Jonsson M, Hellgren C, Wiberg-Itzel E, Akerud H. [Assessment of pain in women randomly allocated to speculum or digital insertion of the Foley catheter for induction of labor.](https://www.ncbi.nlm.nih.gov/pubmed/21615714) Acta Obstet Gynecol Scand. 2011 Sep;90(9):997-1004. doi: 10.1111/j.1600-0412.2011.01197 [↑](#endnote-ref-45)
46. Bujold E, Blackwell SC, Gauthier RJ. [Cervical ripening with transcervical foley catheter and the risk of uterine rupture.](https://www.ncbi.nlm.nih.gov/pubmed/14704239) Obstet Gynecol. 2004 Jan;103(1):18-23. [↑](#endnote-ref-46)
47. Culver J, Strauss RA, Brody S, Dorman K, Timlin S, McMahon MJ. [A randomized trial comparing vaginal misoprostol versus Foley catheter with concurrent oxytocin for labor induction in nulliparous women.](https://www.ncbi.nlm.nih.gov/pubmed/15085496) Am J Perinatol. 2004 Apr;21(3):139-46. [↑](#endnote-ref-47)
48. Mullin PM, House M, Paul RH, Wing DA. [A comparison of vaginally administered misoprostol with extra-amniotic saline solution infusion for cervical ripening and labor induction.](https://www.ncbi.nlm.nih.gov/pubmed/12388962) Am J Obstet Gynecol. 2002 Oct;187(4):847-52. [↑](#endnote-ref-48)
49. Thomas IL, Chenoweth JN, Tronc GN, Johnson IR. [Preparation for induction of labour of the unfavourable cervix with Foley catheter compared with vaginal prostaglandin.](https://www.ncbi.nlm.nih.gov/pubmed/3524549) Aust N Z J Obstet Gynaecol. 1986 Feb;26(1):30-5. [↑](#endnote-ref-49)
50. Owolabi AT, Kuti O, Ogunlola IO. [Randomised trial of intravaginal misoprostol and intracervical Foley catheter for cervical ripening and induction of labour.](https://www.ncbi.nlm.nih.gov/pubmed/16234141) J Obstet Gynaecol. 2005 Aug;25(6):565-8. [↑](#endnote-ref-50)
51. Liu HS, Chang YK, Chu TY, Yu MH, Chen WH. Extra-amniotic balloon with PGE2 versus extra-ovular Foley catheter with PGF2alpha in mid-trimester pregnancy termination. Int J Gynaecol Obstet. 1998 Oct;63(1):51-4. [↑](#endnote-ref-51)
52. St Onge RD, Connors GT. [Preinduction cervical ripening: a comparison of intracervical prostaglandin E2 gel versus the Foley catheter.](https://www.ncbi.nlm.nih.gov/pubmed/7856707) Am J Obstet Gynecol. 1995 Feb;172(2 Pt 1):687-90. [↑](#endnote-ref-52)
53. Delaney S, Shaffer BL, Cheng YW, Vargas J, Sparks TN, Paul K, Caughey AB. [Predictors of cesarean delivery in women undergoing labor induction with a Foley balloon.](https://www.ncbi.nlm.nih.gov/pubmed/25012806) J Matern Fetal Neonatal Med. 2015 Jun;28(9):1000-4. doi: 10.3109/14767058.2014.944154. [↑](#endnote-ref-53)
54. Fitzpatrick CB, Grotegut CA, Bishop TS, Canzoneri BJ, Heine RP, Swamy GK. [Cervical ripening with foley balloon plus fixed versus incremental low-dose oxytocin: a randomized controlled trial.](https://www.ncbi.nlm.nih.gov/pubmed/21793769) J Matern Fetal Neonatal Med. 2012 Jul;25(7):1006-10. doi: 10.3109/14767058.2011.607522.  [↑](#endnote-ref-54)
55. Afolabi BB, Oyeneyin OL, Ogedengbe OK. [Intravaginal misoprostol versus Foley catheter for cervical ripening and induction of labor.](https://www.ncbi.nlm.nih.gov/pubmed/15919393) Int J Gynaecol Obstet. 2005 Jun;89(3):263-7 [↑](#endnote-ref-55)
56. Gelisen O, Caliskan E, Dilbaz S, Ozdas E, Dilbaz B, Ozdas E, Haberal A. [Induction of labor with three different techniques at 41 weeks of gestation or spontaneous follow-up until 42 weeks in women with definitely unfavorable cervical scores.](https://www.ncbi.nlm.nih.gov/pubmed/15925045) Eur J Obstet Gynecol Reprod Biol. 2005 Jun 1;120(2):164-9. [↑](#endnote-ref-56)
57. Kandil M, Emarh M, Sayyed T, Masood A. [Foley catheter versus intra-vaginal misoprostol for induction of labor in post-term gestations.](https://www.ncbi.nlm.nih.gov/pubmed/22434058) Arch Gynecol Obstet. 2012 Aug;286(2):303-7. doi: 10.1007/s00404-012-2292-8 [↑](#endnote-ref-57)
58. [Vahid Roudsari F, Ayati S, Ghasemi M, Hasanzadeh Mofrad M, Shakeri MT, Farshidi F, Shahabian M. Comparison of vaginal misoprostol with foley catheter for cervical ripening and induction of labor.](https://www.ncbi.nlm.nih.gov/pubmed/24363694) Iran J Pharm Res. 2011 Winter;10(1):149-54. [↑](#endnote-ref-58)
59. Sharma KJ, Grubbs BH, Mullin PM, Opper N, Lee RH. [Labor induction utilizing the Foley balloon: a randomized trial comparing standard placement versus immediate removal.](https://www.ncbi.nlm.nih.gov/pubmed/25569680) J Perinatol. 2015 Jun;35(6):390-5. doi: 10.1038/jp.2014.229. [↑](#endnote-ref-59)
60. Al-Taani MI. comparison of prostaglandin E2 tablets or Foley catheter for labour induction in grand multiparas. Easwt Mediten Health J 2004;200410:547-53. [↑](#endnote-ref-60)
61. Pettker CM, Pocock SB, Smok DP, Lee SM, Devine PC. [Transcervical Foley catheter with and without oxytocin for cervical ripening: a randomized controlled trial.](https://www.ncbi.nlm.nih.gov/pubmed/18515515) Obstet Gynecol. 2008 Jun;111(6):1320-6. doi: 10.1097/AOG.0b013e31817615a0. [↑](#endnote-ref-61)
62. Mizrachi Y, Levy M, Bar J, Kovo M. [Induction of labor in nulliparous women with unfavorable cervix: a comparison of Foley catheter and vaginal prostaglandin E2.](https://www.ncbi.nlm.nih.gov/pubmed/26837386) Arch Gynecol Obstet. 2016 Oct;294(4):725-30. doi: 10.1007/s00404-016-4026-9. [↑](#endnote-ref-62)
63. Forgie MM, Greer DM, Kram JJF, et al. Foley Catheter placement for induction of labor with or without stylette: a randomized control trial. Am J Obstet Gynecol 2016;214:397.e1-10. [↑](#endnote-ref-63)
64. Kruit H, Heikinheimo O, Ulander VM, Aitokallio-Tallberg A, Nupponen I, Paavonen J, Rahkonen L. [Management of Foley catheter induction among nulliparous women: a retrospective study.](https://www.ncbi.nlm.nih.gov/pubmed/26508361) BMC Pregnancy Childbirth. 2015 Oct 27;15:276. doi: 10.1186/s12884-015-0715-9. [↑](#endnote-ref-64)
65. Moini A, Riazi K, Honar H, Hasanzadeh Z. [Preinduction cervical ripening with the Foley catheter and saline infusion vs. cervical dinoprostone.](https://www.ncbi.nlm.nih.gov/pubmed/14550602) Int J Gynaecol Obstet. 2003 Nov;83(2):211-3. [↑](#endnote-ref-65)
66. Kruit H, Wilkman H, Tekay A, Rahkonen L. [Induction of labor by Foley catheter compared with spontaneous onset of labor after previous cesarean section: a cohort study.](https://www.ncbi.nlm.nih.gov/pubmed/28406484) J Perinatol. 2017 Jul;37(7):787-792. doi: 10.1038/jp.2017.50. Epub 2017 Apr 13. [↑](#endnote-ref-66)
67. Ghanaie MM, Jafarabadi M, Milani F, Asgary SA, Karkan MF. [A randomized controlled trial of foley catheter, extra-amniotic saline infusion and prostaglandin e2 suppository for labor induction.](https://www.ncbi.nlm.nih.gov/pubmed/24971103) J Family Reprod Health. 2013 Jun;7(2):49-55. [↑](#endnote-ref-67)
68. Guinn DA, Davies JK, Jones RO, Sullivan L, Wolf D. Labor induction in women with an unfavorable Bishop score: randomized controlled trial of intrauterine Foley catheter with concurrent oxytocin infusion versus Foley catheter with extra-amniotic saline infusion with concurrent oxytocin infusion. Am J Obstet Gynecol 2004;191(1): 225–9. [↑](#endnote-ref-68)
69. Perry, KG, Larmon, JE, May, WL, Robinette, LG, Martin, RW. Cervical ripening: a randomized comparison between intravaginal misoprostol and an intracervical balloon catheter combined with intravaginal dinoprostone. Am J Obstet Gynecol. 1998;178:1333–1340 [↑](#endnote-ref-69)
70. Hemlin J, Möller B. [Extraamniotic saline infusion is promising in preparing the cervix for induction of labor.](https://www.ncbi.nlm.nih.gov/pubmed/9492717) Acta Obstet Gynecol Scand. 1998 Jan;77(1):45-9. [↑](#endnote-ref-70)
71. [P.Scott Barrilleaux](javascript:void(0);), [James A. Bofill](javascript:void(0);), [Dom A. Terrone](javascript:void(0);), [Everett F. Magann](javascript:void(0);), [Warren L. May](javascript:void(0);), [John C. Morrison](javascript:void(0);). Cervical ripening and induction of labor with misoprostol, dinoprostone gel, and a foley catheter: A randomized trial of 3 techniques. Am J Obstet Gynecol 2002;186;1124–1129. [↑](#endnote-ref-71)
72. Hill JB, Thigpen BD, Bofill JA, Magann E, Moore LE, Martin JN Jr. A randomized clinical trial comparing vaginal misoprostol versus cervical Foley plus oral misoprostol for cervical ripening and labor induction. Am J Perinatol 2009; 26:33–8. [↑](#endnote-ref-72)
73. Kashanian M, Nazemi M, Malakzadegan A. [Comparison of 30-mL and 80-mL Foley catheter balloons and oxytocin for preinduction cervical ripening.](https://www.ncbi.nlm.nih.gov/pubmed/19232606) Int J Gynaecol Obstet. 2009 May;105(2):174-5. doi: 10.1016/j.ijgo.2009.01.005. Epub 2009 Feb 20. [↑](#endnote-ref-73)
74. Maslovitz S, Lessing JB, Many A. [Complications of trans-cervical Foley catheter for labor induction among 1,083 women.](https://www.ncbi.nlm.nih.gov/pubmed/19488776) Arch Gynecol Obstet. 2010 Mar;281(3):473-7. doi: 10.1007/s00404-009-1136-7. Epub 2009 Jun 2. [↑](#endnote-ref-74)
75. Barkai G, Cohen SB, Kees S, Lusky A, Margalit V, Mashiach S, Schiff E.[Induction of labor with use of a Foley catheter and extraamniotic corticosteroids.](https://www.ncbi.nlm.nih.gov/pubmed/9396910) Am J Obstet Gynecol. 1997 Nov;177(5):1145-8. [↑](#endnote-ref-75)
76. Karjane NW, Brock EL, Walsh SW. [Induction of labor using a foley balloon, with and without extra-amniotic saline infusion.](https://www.ncbi.nlm.nih.gov/pubmed/16449106) Obstet Gynecol. 2006 Feb;107(2 Pt 1):234-9. [↑](#endnote-ref-76)
77. Jozwiak M, Bloemenkamp KW, Kelly AJ, Mol BW, Irion O, Boulvain M. Mechanical methods for induction of labour. Cochrane Database Syst Rev 2012;3:CD001233. [↑](#endnote-ref-77)
78. Ten Eikelder M, van Baaren GJ, Oude Rengerink K, Jozwiak M, de Leeuw JW, Kleiverda G, Evers I, de Boer K, Brons J, Bloemenkamp K, Mol BW. [Comparing induction of labour with oral misoprostol or Foley catheter at term: cost-effectiveness analysis of a randomised controlled multi-centre non-inferiority trial.](https://www.ncbi.nlm.nih.gov/pubmed/28440898) [Comparing induction of labour with oral misoprostol or Foley catheter at term: cost-effectiveness analysis of a randomised controlled multi-centre non-inferiority trial.](https://www.ncbi.nlm.nih.gov/pubmed/28440898) [↑](#endnote-ref-78)
79. Husain S, Husain S, Izhar R. [Oral misoprostol alone versus oral misoprostol and Foley's catheter for induction of labor: A randomized controlled trial.](https://www.ncbi.nlm.nih.gov/pubmed/28561987) J Obstet Gynaecol Res. 2017 Aug;43(8):1270-1277. doi: 10.1111/jog.13354.  [↑](#endnote-ref-79)
80. Levy R, Kanengiser B, Furman B, Ben Arie A, Brown D, Hagay ZJ. A randomized trial comparing a 30-mL and an 80-mL Foley catheter balloon for preinduction cervical ripening. Obstet Gynecol. 2004; 191:1632–1636. [↑](#endnote-ref-80)
81. Sandberg EM, Schepers EM, Sitter RL, Huisman CM, Wijngaarden WJ. [Foley catheter for induction of labour filled with 30mL or 60mL: A randomized controlled trial.](https://www.ncbi.nlm.nih.gov/pubmed/28260689) [Foley catheter for induction of labour filled with 30mL or 60mL: A randomized controlled trial.](https://www.ncbi.nlm.nih.gov/pubmed/28260689) [↑](#endnote-ref-81)
82. Levy R, Ferber A, Ben-Arie A, Paz B, Hazan Y, Blickstein I, Hagay ZJ. [A randomised comparison of early versus late amniotomy following cervical ripening with a Foley catheter.](https://www.ncbi.nlm.nih.gov/pubmed/11888099) BJOG. 2002 Feb;109(2):168-72. [↑](#endnote-ref-82)
83. Jeanine F. Carbone, Methodius G. Tuuli, Patricia J. Fogertey, Kimberly A. Roehl, George A. Macones. Combination of Foley Bulb and Vaginal Misoprostol Compared With Vaginal Misoprostol Alone for Cervical Ripening and Labor Induction A Randomized Controlled Trial. Obstet Gynecol 2013;121:247–52 [↑](#endnote-ref-83)
84. Onah HE. [Effect of the Foley catheter and synchronous oxytocin administration on cervical ripening.](https://www.ncbi.nlm.nih.gov/pubmed/12834946) Int J Gynaecol Obstet. 2003 Jul;82(1):71-2 [↑](#endnote-ref-84)