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**RESEARCH PROPOSAL FOR MASTER OF MEDICINE**

**(OBSTETRICS AND GYNAECOLOGY)**

**DEPARTMENT OF OBSTETRICS AND GYNAECOLOGY**

**UNIVERSITI MALAYA**

**TITLE**

**Induction of Labour In One Previous Caeserean Delivery And History Of Vaginal Birth(s) With Foley Catheter Versus Dinoprostone Controlled-Released Vaginal Insert: A Randomised Trial**

**CANDIDATE:**

**DR NOR DALILA SHAMSUDDIN**

**MGG180007**

**SUPERVISOR:**

**PROFESSOR DR. TAN PENG CHIONG**

**ASSOCIATE PROFESSOR DR AIZURA SYAFINAZ AHMAD ADLAN**

TABLE OF CONTENTS

TITLE

INTRODUCTION AND LITERATURE REVIEW

OBJECTIVES OF STUDY

RESEARCH HYPOTHESIS

ENDPOINTS

METHODOLOGY

ETHICAL CONSIDERATION

SAMPLE SIZE CALCULATION

STATISTICAL ANALYSIS

TECHNIQUE OF DATA COLLECTION

STUDY PROTOCOL FLOW CHART

CASE REPORT FORM

GANNT CHART

REFERENCES

**TITLE**

Induction Of Labour In One Previous Caesarean Delivery And History Of Vaginal Birth(s) With Foley Catheter Versus Dinoprostone Controlled-Released Vaginal Insert: A Randomised Trial

**INTRODUCTION AND LITERATURE REVIEW**

Caesarean delivery rate is increased globally, accounting for 12% in 2000 to 21% in 2015. Papers published in the Lancet shows that 106 out of 169 countries have caesarean section rate above 10%-15% of births that is thought to be optimal (Betrán et al., 2018; Boerma et al., 2018; Sandall et al., 2018). As caesarean section is rising globally, more and more women embarking on pregnancy with previous Caesarean scar.

Trial of labour after caesarean delivery (TOLAC) refers to a planned attempt to deliver vaginally by a woman who had a previous caesarean section. TOLAC provides women who desire a vaginal delivery in achieving a vaginal birth after caesarean delivery (VBAC). VBAC is actively promoted and counselled to pregnant women with one previous scar who has no contraindication for TOLAC.

A meta-analysis (n=103188 VBAC labours) reported a success rate of planned VBAC of 74% (Guise et al., 2004; Mozurkewich & Hutton, 2000) . However, previous vaginal delivery, particularly previous successful VBAC is associated with higher success rate of 85-90% (Landon et al., 2005)and it independently associated with a reduction of uterine rupture risk (Barger et al., 2011; Grobman et al., 2008; Smith et al., 2004; Stamilio & Shanks, 2008).

Induction of labour is an option for women with one previous scar undergoing TOLAC. ("ACOG Practice Bulletin No. 205: Vaginal Birth After Cesarean Delivery," 2019)

 After globally acceptance of planned vaginal birth after caesarean section (VBAC), the mode of induction is still a matter of debate and requires further discussion. To date, there is no consensus with regards to induction of labour and controversy over optimal method for induction. (Jozwiak & Dodd, 2013).

Risk of uterine rupture in this population remain the main concern of care providers. Rates of uterine rupture differ according to whether the VBAC is spontaneous (0.15-0.4%), induced (0.54-1.4%) or augmented (0.9-1.91%) (Dekker et al., 2010; Fitzpatrick et al., 2012; Landon et al., 2004).
 A 2021 metanalysis observational studies on Oxytocin use in trial of labour after caesarean and its relationship with risk of uterine rupture in women with one previous caesarean section showed a higher risk of uterine rupture in induced labour and oxytocin use may increase the risk (Zhang et al., 2021).

Other method of induction using mechanical devices such as transcervical foley catheter have been used for priming and induction of labour. In women with an unscarred uterus, mechanical induction shows a lower incidence of uterine hyperstimulation and similar caesarean section rate compared with locally applied prostaglandins (Connolly et al., 2017; Jozwiak et al., 2014; Løkkegaard et al., 2015; Ten Eikelder et al., 2016; Vaknin et al., 2010).

A 2018 trial report comparing foley catheter with controlled-release dinoprostone vaginal insert for labour induction after one previous scar 51% and 59% respectively. But the rate is much reduced (18%) [n=3][3.1 (95% CI 1.0-9.5)] in induction with vaginal insert in women with history of vaginal delivery . (Sivaranjani, 2018)

At an individual level, VBAC is associated with decreased maternal morbidity and a decreased risk of complications in future pregnancies as well as a decrease in the overall caesarean delivery rate at the population level (Curtin et al., 2015; Little et al., 2008; Menacker & Curtin, 2001). However, although TOLAC is appropriate for many women, several factors increase the likelihood of a failed trial of labour (Wu et al., 2019), which in turn is associated with increased maternal and perinatal morbidity when compared with a successful trial of labor (ie, VBAC) and elective repeat caesarean delivery (Hibbard et al., 2001; Landon et al., 2005; Macones et al., 2005).

 Therefore, based on these observations, it inspires us to perform a study of foley catheter and dinoprotone controlled released vaginal insert in the induction of labour of women with one previous caesarean section and history of vaginal birth(s) with unripe cervix at term. The objective of this study is to compare the efficacy of transcervical foley catheter and dinoprostone controlled release vaginal insert by exploring the number of caesarean rates.

**OBJECTIVE OF STUDY**

To compare transcervical Foley catheter and Dinoprostone controlled-released vaginal insert for the induction of labour after one caesarean delivery with history of vaginal birth(s).

**RESEARCH HYPOTHESIS**

Induction of labor with Dinoprostone controlled-released vaginal insert in women with one previous caesarean section and history of vaginal birth(s) will result in lower caesarean rate and higher patient satisfaction with their birth process.

**PRIMARY ENDPOINT**

1. Caesarean section rate (To obtain after delivery)

 **SECONDARY ENDPOINT

Maternal outcomes**

1. Use of additional method for cervical ripening (To obtain after delivery)
2. Bishop score upon 1st assessment upon removal of induction of labor method (To obtain after removal of induction device)
3. Spontaneous rupture of membrane or amniotomy (To obtain after delivery)
4. Use of oxytocin for intrapartum augmentation (To obtain after delivery)
5. Duration of oxytocin use (To obtain after delivery)
6. Type of analgesia in labor (To obtain after delivery)
7. Estimated blood loss for delivery (To obtain after delivery)
8. Fever ≥ 38’C (from induction to patient discharge)
9. Complications (during induction, intrapartum and postpartum like scar rupture, blood transfusion, maternal admission to ICU/HDU, hysterectomy, re-laparotomy, others)
10. Uterine hyperstimulation syndrome (first 24 hours – to obtain after delivery)
11. Terbutaline use (To obtain after delivery)
12. Maternal satisfaction with induction method using a 10 visual numerical rating scale (scored from 0 to 10); (To obtain upon removal / dislodge of the induction device)
13. Pain score during the insertion of device (To obtain as soon as possible after placement of induction device)

**Neonatal outcomes**

1. APGAR score at 1 and 5 minutes (To obtain after delivery)
2. Arterial cord pH (To obtain after delivery)
3. Birth weight (To obtain after delivery)
4. Neonatal admission and indication (To obtain after delivery)
5. Neonatal complication (To obtain after delivery)

**METHODOLOGY**

Study design
Single centre, open label, randomised trial

Population of Study
Women with unfavourable cervix undergoing cervical ripening and induction of labour at term with one previous caesarean delivery with history of vaginal birth(s) in University Malaya Medical Centre, Kuala Lumpur

Inclusion criteria

Scheduled induction of labour

One previous scar

History of vaginal birth(s)

Aged 18 years and above

Gestational age of > 37 weeks at enrolment

Unfavorable cervix (Bishop Score ≤ 6)

Singleton pregnancy

Cephalic presentation

Reassuring pre-induction fetal cardiotocography (CTG)

Intact membranes

Absence of significant contraction ≥ 2 in 10 minutes

Exclusion criteria

Preference for Elective repeated caesarean section

Allergic to latex

Allergic to prostaglandin

Inability to give consent

Known gross fetal anomaly

Absolute contraindication to vaginal delivery

Estimated fetal weight of < 2kg or ≥ 4kg

Withdrawal criteria

Participant not keen to continue or request to withdraw from participation

**METHODS**

This study is a randomized trial to compare Foley Catheter with Dinoprostone Controlled- Released Vaginal Insert for induction of labour in women with 1 previous caesarean delivery and history of vaginal birth(s).

The decision to proceed with induction of labour is made by the care provider based on standard clinical grounds and specific consenting with the option for repeat Caesarean always on offer as an alternative.

Ethical approval will be obtained from the Medical Ethics Committee, University of Malaya Medical Centre prior initiation of the study.

 All pregnant women with one previous caesarean delivery and history of vaginal birth who has been decided for induction of labour and who fulfils inclusion criteria will be recruited in the study. Those eligible will be counselled regarding the study and patient information sheet will also be given. Time will be given to patient to make her decision in participating in this study. If the women agreed to participate in this study, written consent will be obtained. Women who choose not to participate will receive standard care and participants who decided to withdraw may do so without having to give a reason and their care will not be affected.

 During admission, a pre-induction cardiotocography ( CTG ) and assessment of Bishop Score will be done. Participants are excluded from the study if the CTG is non-reassuring or Bishop score >6.

 Participants that suitable for the study will be randomised into 2 groups (Foley catheter or controlled-release dinoprostone vaginal insert).

 The randomization sequence will be generated using random number generator at random.org website. The random allocation sequences are placed in a sealed opaque envelope in strict number order. Randomization is by taking the lowest numbered sealed remaining. Blinding of care provider and participant is deemed impractical due to the nature of the intervention.

**FOLEY’S CATHETER GROUP:**

* Participants who are randomised into this group will be induced using Foley catheter.
* Foley catheter size 16F will be used to ripen the cervix
* Under a sterile technique, Bishop scoring will be quantified
* A 16 French Foley catheter will be inserted digitally into the cervix under aseptic technique
* Participants are positioned in the dorsal recumbent position with thighs comfortably abducted, knee flexed and feet flat on the normal hospital bed.
* The foley catheter tip will be guided through the external cervical os to about 4cm beyond the os by the operator’s gloved hand and fingers with the aid of a water-soluble lubricant.
* The catheter balloon will be inflated with 60ml of sterile water and gentle traction is applied till the balloon meet resistance.
* The external end of the catheter is spigot and then strap to the thigh without additional tension (Chia et al., 2020)
* Speculum guided insertion can be attempted if digital insertion failed (Chia et al., 2020)
* The Foley catheter will be removed if spontaneous rupture of membrane, abnormal CTG, uterine hyperstimulation or tachysystole, excessive pain or vaginal bleeding, or after 24 hours of placement

**DINOPROSTONE CONTROLLED-RELEASE VAGINAL INSERT GROUP:**

* Participants who are randomised into this group will be induced with Dinoprostone controlled-Released Vaginal Insert.
* Participants are positioned in the dorsal recumbent position with thighs comfortably abducted.
* Under a sterile technique, pick up the insert between 2 fingers and lightly coat with water-miscible lubricant.
* The insert will be gently placed transversely in the posterior vaginal fornix. Take care not to dislodge the insert when removing the fingers.
* The retrieval tape will be slightly outside the introitus for retrieval as required
* The controlled-release Dinoprostone vaginal insert will be removed if spontaneous rupture of membrane, abnormal CTG, uterine hyperstimulation or tachysystole, excessive pain or vaginal bleeding, side effect of dinoprostone such as nausea, vomiting, hypotension or tachycardia and after 24 hours of placement.

**FOR BOTH GROUPS:**

* For both arms, time of induction will be recorded after the insertion of the intervention material.
* CTG monitoring will be performed after the intervention and only stop when it is reassuring
* Subsequent CTG will be done at the minimum of every 6 hourly whilst patient is on the intervention devise.
* CTG can be performed by care provider in interim event (ie – regular contraction suggestive of labour progression)
* Participants in both arms will be assessed after 24 hours and the catheter or insert will be removed if not dislodged spontaneously.
* After 24-hour of intervention with foley or insert, if the cervix is favourable, amniotomy will be done when the cervical dilatation is at least 2-3cm.
* If the cervix is not favourable after 24 hours, the participants will be counselled and given option of continue with labour induction or to proceed with repeat caesarean delivery.
* If patient opted for continuation of induction of labour, cross over to the other intervention can be initiated after discuss with care provider.
* Beyond 48 hours, if the cervix is still unfavourable, further discussion with patient and care provider with consultant will be made.
* Intrapartum management of participant’s labour and decision making on delivery is under discretion of care provider according to standard practical practice.

**ETHICAL CONSIDERATIONS**

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. Women who choose not to participate will receive standard care and participants who decided to withdraw may do so without having to give a reason and their care will not be affected.

**SAMPLE SIZE CALCULATION**

Base on the study done in our centre by Sofiah et al. in 2018, we found that the caesarean delivery rate in women with one previous caesarean section with vaginal birth in Dinoprostone Controlled-released vaginal insert arm was 18%, while in the Foley arm was 54%.

Applying α of 0.05, power of 80%, one-to-one randomisation, 27 participants are required in each arm. Factoring a 10% drop-out rate, a total of 60 participants are required for a powered study (30 participants in each arm).

**STATISTICAL ANALYSIS**

Data will be entered into SPSS statistical software. Normally distributed continuous data will be analyzed with the Student’s t test. Chi square test will be used for categorical or nominal data and Mann-Whitney U test will be used on non-normally distributed or ordinal data.

**ABBREVIATIONS**

APGAR score - Appearance, Pulse, Grimace, Activity, and Respiration score
CTG – Cardiotocography
HDU – High dependency unit
ICU – Intensive care unit
IOL – Induction of labour
LSCS – Lower segment caesarean section
NICU – Neonatal intensive care unit
PNW – Postnatal ward
SCN – Special care nursery
SVD – Spontaneous vaginal delivery
TOLAC – Trial of labour after caesarean delivery
VBAC – Vaginal birth after caesarean delivery

**TECHNIQUES FOR DATA COLLECTION**

**STUDY INSTRUMENT:**

1. **Transcervical Foley Catheter (Figure 1)**

It is an indwelling catheter made of latex rubber. It is a mechanical induction of labour method where, Transcervical foley catheter 16 F will introduced into the cervix beyond internal os and the bulb of the catheter inflated with 60ml of sterile water and the catheter will be strapped to the thigh with gentle traction.



 Figure 1

 **2. Sustained-release Dinoprostone Vaginal Insert (Figure 2 )**

The sustained-release dinoprostone vaginal insert used in the trial was Cervidil®, Ferring Pharmaceuticals Inc., New Jersey, USA: an item at our center’s formulary. Trial devices were supplied free of charge to all participants.



 Figure 2

 **3. Modified Bishops score ( Figure 3 )**

It is a group of measurements made at vaginal examination. It is used to assess whether the cervix is favourable or not. The score is based on the station, dilation, effacement (or length), position and consistency of the cervix. A Bishop score of less than 6 means that your cervix may not be ready for labour.

**Figure 3: modified Bishop score**

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

**STUDY PROTOCOL FLOW CHART**

Counsel and patient information sheet will be given.
Obtain consent once patient agreeable to participate in the study

Assess for eligibility & recruitment form

CTG and Bishop score

Randomized in 2 groups

Insertion of Foley catheter size 16 F

Insertion of dinoprostone sustained release vaginal insert

Participant can withdraw from participating in any point of this study.

CTG post insertion and at minimum 6 hourly

Reassessment after 24hours / earlier if indicated.
Bishop score upon removal of catheter or vaginal insert

Unfavourable Bishop Score

Favourable Bishop Score

Cross over intervention

LSCS

Amniotomy

Bishop score upon removal of catheter or vaginal insert

Continuation of care as per UMMC protocol

Primary and secondary outcome

Unfavourable Bishop Score

Favourable Bishop Score

**CASE REPORT FORM**

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Study number

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

BMI : \_\_\_\_\_\_\_\_\_\_\_\_\_

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 : Year : \_\_\_\_\_\_\_ indication : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Obstetric history

(Year / mode of delivery / birth weight )

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| 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 : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date / time of insertion : (\_\_\_\_\_\_\_\_\_\_\_ / \_\_\_\_\_\_\_\_\_\_\_ )

* Bishop Score at removal : \_\_\_\_\_\_\_\_\_\_\_\_\_

Assessment performed by : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date / time of removal : (\_\_\_\_\_\_\_\_\_\_\_ / \_\_\_\_\_\_\_\_\_\_\_ )

Indication of early removal : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Time of insertion

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

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

Time of entering active phase : \_\_\_:\_\_\_(min: sec)

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

2. Foley Insertion failure rates

Successful?

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

Second method of induction

 Yes (please specify \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ )

No

3. Use of additional prostaglandin for cervical ripening?

* Yes Please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

No

4. Use of oxytocin for intrapartum augmentation?

 Yes ( maximum dose : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ ml/hour )

No

 5. Mechanism if membrane rupture

Amniotomy

Spontaneous rupture of membrane

6. Use of regional analgesia in labour?

1. Yes Please specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

No

7. Mode of Delivery:

* SVD

Caesarean section. Indication/s: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Instrumental delivery: Forceps / Vacuum. Indication/s: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

8. Time of delivery : Date \_\_\_/ \_\_\_/ \_\_\_ (dd/mm/yy)

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

9. Estimated blood loss postdelivery: \_\_\_\_\_\_\_\_\_\_ ml

10. Temperature: Intrapartum \_\_\_\_\_\_ 0C

Postnatal up to discharge \_\_\_\_\_\_ 0C

 11. Uterine hyperstimulation

 Yes

No

 12. Tertbutaline use

 Yes

No

 13. Maternal Complications

 Yes

 Scar rupture

 Blood transfusion

 Maternal admission to ICU/HDU

 Hysterectomy

 Re-laparotomy

 Maternal mortality

 Damage to internal organ ( bowel / bladder / ureter )

 Others \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

No

**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 : \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

5. Neonatal complication

 Yes

  Birth trauma

 Death of baby (intrapartum / neonatal / perinatal )

 Hypoxic ischemic encephalopathy or need for therapeutic hypothermia

 Meconium aspiration syndrome

 Need for respiratory support

 Neonatal infection

 Neonatal seizure

 Others \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

No

**THANK YOU FOR YOUR PARTICIPATION IN THIS STUDY**
We will be most delightful if you could complete this questionnaire for us to know your views about the induction of labour.

All you need to do is to tick the appropriate box that best describe how you feel.

Try not to dwell too long on each question. Don’t worry, there are no or right answer. ☺
Choose the answer that come closest to how have been feeling generally.

1. Pain score during the insertion of induction device ( To obtain after the insertion of the device)

**What is your pain score during the insertion of Foley catheter / vaginal insert procedure? Please circle the score below :**

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 0 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |

Worst pain possible

Moderate pain

No pain



1. Maternal satisfaction with their care since allocation to the intervention. (To obtain upon removal / dislodge of device)

**What is your satisfaction score since insertion of the catheter until the removal of the catheter or insertion vaginal pessary till the review? Please circle the score below:**

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

Very satisfied



Very dissatisfied

1. Would you recommend this method of induction

 to your friend for your future pregnancy

**GANNT CHART**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Duration** | **April – May 2021** | **May – June 2021** | **July – Aug 2021** |  **Sept - Oct 2021** | **Nov – Dec 2021** | **Jan – Feb 2021** |
| **Literature review** | ✓ |   |   |   |   |   |
| **Proposal preparation****& presentation** | ✓ |  |   |   |   |   |
| **Ethics review** |  ✓ | ✓ |  |   |   |   |
| **Data collection** |   |  ✓ |  ✓ |  ✓ |   ✓ |   |
| **Data analysis and writing** |   |   |   |   |  ✓ |   ✓ |
| **Thesis submission** |   |   |   |   |   |  ✓ |

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