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Comparing two methods of labour induction in term pregnant women who had one previous Caesarean delivery and history of vaginal birth (s)

Submission date
10/08/2021

Recruitment status
No longer recruiting

Registration date
19/08/2021

Overall study status
Completed

Last Edited
11/08/2023

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Labour induction is the stimulation of uterine contractions during pregnancy before labour begins on its own to achieve a vaginal birth. It is done because earlier delivery is considered to be safer than allowing the pregnancy to continue in certain cases, and occasionally for logistic or maternal preference.
Induction of labour in women with a Caesarean section is associated with a risk of scar rupture and a higher failure rate resulting in a repeat Caesarean section. However, it is considered a safe process when conducted in a well-resourced setting after careful consideration and counselling. The standard method of induction can be medical or mechanical. In medically induced labour for unfavourable cervix, a prostaglandin will be given into the vagina. Prostaglandin will soften the cervix and can cause contractions. A new preparation of prostaglandin has been developed which is in vaginal insert form. It contains a reservoir that slowly releases the drug; compared to vaginal tablet forms where absorption can be too fast leading to intense contractions. If intense contractions are produced, the insert can be easily removed by pulling out the thread.
Mechanically induced labour uses physical pressure to stimulate the cervix. A Foley catheter is commonly used in this method. The tube is inserted through the cervix and the balloon is filled with water and the outside section of the tube is taped to the woman's thigh to apply gentle downward pressure. The pressure of the balloon causes softening and opening (ripening) of the cervix, but usually without contractions. It is placed for 24 hours or removed earlier if medically indicated. Breaking the waters and an oxytocin drip to produce contractions is more often needed in labour induction with the Foley catheter, compared to when prostaglandins are used.
This study aims to compare the use of the Foley catheter and dinoprostone controlled released vaginal insert (a type of prostaglandin) in women with full-term pregnancies who have previously had one Caesarean section and a history of vaginal birth(s). The two methods of labour induction will be compared in terms of caesarean section rate.

Who can participate?
Women at over 37 weeks of pregnancy who have had one previous Caesarean and history of vaginal birth(s) and who need induction of labour.

What does the study involve?
Participants will be randomly allocated to the dinoprostone controlled-release vaginal insert group or the Foley catheter group. In the dinoprostone group, the insert will be placed in the vagina. For women in the Foley catheter group, the catheter will be inserted and the balloon inflated with 60 ml of water. In both groups, the vaginal insert or Foley catheter will be removed if there are any problems or if it is still inside the vagina after 24 hours.

What are the possible benefits and risks of participating?
A possible benefit is a lower caesarean section rate, reducing repeated caesarean section complications for mother and baby. There is a small risk of failure of induction and a Caesarean delivery will be needed. The vaginal insert can cause uterine hyperstimulation, which involves very strong and long-lasting contractions or contractions every 2 minutes on average. This can result in problems for the baby or rupture of the womb. If uterine hyperstimulation occurs, the insert must be removed immediately and a tocolytic agent (medication to reduce uterine contraction) can be considered.

Where is the study run from?
University Malaya Medical Centre (Malaysia)

When is the study starting and how long is it expected to run for?
April 2021 to December 2022

Who is funding the study?
University Malaya (Malaysia)

Who is the main contact?
1. Dr Nor Dalila Shamsuddin
dalila.shamsuddin@gmail.com
2. Prof. Dr Tan Peng Chiong
pctan@um.edu.my

Contact information

Type(s)
Scientific

Contact name
Dr Nor Dalila Shamsuddin

Contact details
University Malaya Medical Centre
Lembah Pantai
Kuala Lumpur
Malaysia
59100
+60 (0)379494422
dalila.sham@ummc.edu.my

Type(s)
Scientific

Contact name
Dr Nor Dalila Shamsuddin

Contact details
University Malaya Medical Centre
Lembah Pantai
Kuala Lumpur
Malaysia
59100
+60133267990
dalila.shamsuddin@gmail.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
MREC ID: 2021426-10091

Study information

Scientific Title
Induction of labour in one previous Caesarean delivery and history of vaginal birth(s) with Foley catheter versus controlled-release dinoprostone vaginal insert: a randomised trial

Acronym
FocaCer

Study objectives
Induction of labour with controlled-release dinoprostone vaginal insert in women with one previous caesarean delivery and history of vaginal birth(s) will result in lower caesarean rate and higher patient satisfaction with their birth process.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/07/2021, University of Malaya Medical Centre Medical Research Ethics Committee (Lembah Pantai, 59100 Kuala Lumpur, Malaysia; +60 (0)3 7949 8473; email: not applicable), ref: MREC ID: 2021426-10091

Study design
Randomized control trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Labour induction

Interventions
This study is a randomised trial to compare Foley catheter with controlled-release dinoprostone vaginal Insert for induction of labour in women with one 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.

Pregnant women with one previous caesarean delivery and history of vaginal birth(s) who has been decided for induction of labour and who fulfil the inclusion/exclusion criteria will be recruited. Those eligible will be counselled regarding the study and a patient information sheet will also be given. Time will be given for the patient to make her decision to participate in this study. If the woman agrees 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.

On admission, a pre-induction cardiotocography (CTG) and assessment of Bishop Score will be carried out. Participants are excluded from the study if the CTG is non-reassuring or Bishop score is 6 or more. Participants who are suitable for the study will be randomised into two groups (Foley catheter or controlled-release dinoprostone vaginal insert). The randomization sequence will be generated using a random number generator at the random.org website.

In the Foley catheter group, participants will be induced using a 16F Foley catheter under the aseptic technique. The catheter balloon will be inflated with 60 ml of sterile water and gentle traction is applied until the balloon meets resistance. The external end of the catheter is spigot and then strapped to the thigh without additional tension. The Foley catheter will be removed if there is a spontaneous rupture of membrane, abnormal CTG, uterine hyperstimulation or tachysystole, excessive pain or vaginal bleeding, or after 24 hours of placement

While in the controlled-release dinoprostone vaginal insert group, participants will be induced with a controlled-release dinoprostone vaginal Insert. The insert will be inserted under sterile

technique and only will be removed if there is a spontaneous rupture of membrane, abnormal CTG, uterine hyperstimulation or tachysystole, excessive pain or vaginal bleeding, a side effect of dinoprostone such as nausea, vomiting, hypotension or tachycardia and after 24 hours of placement.

In both groups, CTG monitoring will be performed after the intervention and subsequent CTG will be carried out at a minimum of every 6 hours whilst the patient is on the intervention device or as per care provider in interim event (i.e. 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 hours of intervention with foley or insert, if the cervix is favourable, an amniotomy will be carried out when the cervical dilatation is at least 2-3 cm. If the cervix is not favourable after 24 hours, the participants will be counselled and given the option of continuing with labour induction or proceeding with repeat caesarean delivery.

If the patient opts for the continuation of induction of labour, a cross over to the other intervention can be initiated after a discussion with the care provider. Beyond 48 hours, if the cervix is still unfavourable, there will be a further discussion between the patient and care provider with the consultant. Intrapartum management of participant's labour and decision making on delivery is at the discretion of the care provider according to standard practical practice.

Intervention Type
Procedure/Surgery

Primary outcome measure
Caesarean section rate collected from patients' medical records after the patient has delivered and measured after the completed sample size for this study

Secondary outcome measures
Maternal outcomes:
1. Use of additional method for cervical ripening, taken from patients' medical records after delivery
2. Bishop score upon first assessment upon removal of induction of labor method
3. Spontaneous rupture of membrane or amniotomy, taken from patients' medical records after delivery
4. Use of oxytocin for intrapartum augmentation, taken from patients' medical records after delivery
5. Duration of oxytocin use, taken from patients' medical records after delivery
6. Type of analgesia in labor, taken from patients' medical records after delivery
7. Estimated blood loss for delivery, taken from patients' medical records after delivery
8. Fever ≥38°C, taken from patients' medical records and collected from initiation of induction of labour until patient discharge
9. Complications (scar rupture, blood transfusion, maternal admission to ICU/HDU, hysterectomy, re-laparotomy, others), taken from patients' medical records during induction of labour, intrapartum and postpartum until patient discharge
10. Uterine hyperstimulation syndrome, taken from patients' medical records from first 24 hours from initiation of induction of labour and obtained after delivery
11. Terbutaline use, taken from patients' medical records after delivery
12. Maternal satisfaction with induction method using a visual numerical rating scale (scored from 0 to 10), obtained upon removal/dislodge of the induction device

13. Pain during the insertion of the device, measured using the visual analogue score (VAS) as soon as possible after placement of induction device

Neonatal outcomes:
1. APGAR score at 1 and 5 minutes, measured using the APGAR score scoring system after delivery
2. Arterial cord pH, taken from arterial cord blood gas and obtained after delivery
3. Birth weight, taken from patients' medical records after delivery
4. Neonatal admission and indication, taken from patients' medical records after delivery
5. Neonatal complications, taken from patients' medical records after delivery

Overall study start date
01/04/2021

Completion date
31/12/2022

Eligibility

Key inclusion criteria
1. Scheduled induction of labour
2. One previous scar
3. History of vaginal birth(s)
4. Aged 18 years and above
5. Gestational age of >37 weeks at enrolment
6. Unfavorable cervix (Bishop Score <6)
7. Singleton pregnancy
8. Cephalic presentation
9. Reassuring pre-induction fetal cardiotocography (CTG)
10. Intact membranes
11. Absence of significant contraction ≥2 in 10 minutes

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
60 patients with 30 in each arm

Key exclusion criteria
1. Preference for elective repeated caesarean section
2. Allergic to latex

3. Allergic to prostaglandin
4. Inability to give consent
5. Known gross fetal anomaly
6. Absolute contraindication to vaginal delivery
7. Estimated fetal weight of <2 kg or ≥4 kg

Date of first enrolment
23/08/2021

Date of final enrolment
31/08/2022

Locations

Countries of recruitment
Malaysia

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

Sponsor information

Organisation
University of Malaya

Sponsor details
Obstetrics and Gynaecology Department
University Malaya Medical Centre
Lembah Pantai
Kuala Lumpur
Malaysia
59100
+60 (0)3 7949 2473
grow@ummc.edu.my

Sponsor type
University/education

Website
https://www.um.edu.my/

ROR
https://ror.org/00rzspn62

Funder(s)

Funder type
University/education

Funder Name
Universiti Malaya

Alternative Name(s)
University of Malaya, University Malaya, Malayan University, UM

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Malaysia

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/01/2023

Individual participant data (IPD) sharing plan
The raw data generated during and/or analysed during the current study are/will be available upon request from Nor Dalila Shamsuddin (dalila.sham@ummc.edu.my) and the results will be available publicly at https://v1.nmrr.gov.my/fwbLoginPage.jsp under the directory of medical research.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 2	01/06/2021	16/08/2021	No	Yes
Protocol file	version 2	02/06/2021	16/08/2021	No	No