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Induction of labour with balloon catheter or balloon catheter with controlled-release dinoprostone vaginal insert

Submission date
16/11/2018

Recruitment status
No longer recruiting

Registration date
03/12/2018

Overall study status
Completed

Last Edited
10/01/2022

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Current plain English summary as of 10/12/2018:
Background and study aims
Labour is induced (started artificially) when earlier delivery is consider to be safer than allowing the pregnancy to continue and also occasionally for logistical convenience or maternal preference. Induction of labour in a woman having her first baby where the cervix (neck of the womb) is unripe (long, close and not soft) remains a challenge because it often takes more than 24 hours to achieve delivery and in up to 2 in 5 women, induction is unsuccessful and Caesarean delivery is needed.
The standard method of induction of labour when the cervix is not favourable (does not show changes needed for birth to occur) is to use drugs similar to prostaglandin (a signalling chemical naturally found in the body) given into the vagina. Prostaglandin softens the cervix and can also cause contractions, triggering labour. Recently, a new preparation of prostaglandin has been developed. This is applied as a vaginal insert containing a reservoir that slowly releases the drug. This means that the prostaglandin is released more gradually compared to vaginal tablet forms where absorption can be too fast, potentially leading to intense contractions. If intense contractions are produced, the insert can be easily removed.
Another method is to use physical pressure to stimulate the cervix, rather than a drug. A Foley catheter is a tube with a balloon at one end. The tube is inserted through the cervix so that the balloon is just inside the womb resting on the internal opening of the cervix. 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 balloon pressure on the internal opening of the cervix causes softening and opening (ripening) of the cervix, usually without contractions. 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 concurrent use of the Foley catheter and dinoprostone (a type of prostaglandin) with Foley catheter alone in women who have never give birth at term. The two methods of labour induction will be compared in terms of the time taken from induction to birth and the mother's satisfaction with the birth process.

Who can participate?
Women aged over 18 years at term with no previous pregnancy beyond 20 weeks with an unripe cervix who need induction of labour.

What does the study involve?
All participants will have a Foley catheter inserted with the use of a speculum (a tool to enable the practitioner to see the cervix) into the uterus (womb) through the cervix and the balloon will be filled with 60 ml of sterile water. This insertion usually takes a few minutes and requires the participant to be on her back in a bed. Participants who are randomised to Foley catheter plus controlled-release dinoprostone insert will then have the insert placed in the upper vagina. This should take only seconds. The Foley catheter tubing will be taped onto the thigh with minimal tension. The controlled-release dinoprostone insert has a string attached that will hang outside the vagina and allow quick and easy removal of the insert.
Participants will be monitored regularly, including with an electronic fetal heart rate monitor, at least every 6 hours. The Foley catheter and controlled-release dinoprostone insert will be removed after 24 hours unless they have already been expelled or removed earlier for medical reasons.
After device removal at 24 hours, participants will receive standard labour care as decided with their care provider in accordance with your wishes. If the cervix is still unripe and the baby and mother are in good condition, additional attempts to ripen the cervix might be considered.
At 6 hours after device placement, pain will be assessed with a pain score (numerical rating scale 0-10) and after delivery, participants will be assessed on her satisfaction with the labour induction using a numerial rating scale 0-10 and Likert scale.

What are the possible benefits and risks of participating?
It is not known which method has a better outcome or whether the results will be much the same for the two methods. If one method is better than the other, the time to delivery might be shorter and the patients might be more satisfied in one group and less satisfied in the other group. The investigators do not expect a difference in Caesarean delivery rate.

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

When is the study starting and how long is it expected to run for?
February 2018 to October 2019

Who is funding the study?
The Department of Obstetrics and Gynecology, University Malaya Medical Center

Who is the main contact?
1. Dr. Naumi Binti Laboh; naumigsm@hotmail.com (public contact)
2. Professor Tan Peng Chiong; tanpengchiong@yahoo.com
3. Associate Professor Vallikkannu Narayanan; valli2valli@gmail.com

Previous plain English summary:
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This study aims to compare use of the Foley catheter and dinoprostone (a type of prostaglandin) delivered as a vaginal insert in women who have never previously given birth. The two methods of labour induction will be compared in terms of the time taken from induction to birth and the mother's satisfaction with the birth process.

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Who is the main contact?
1. Dr. Naumi Binti Laboh; naumigsm@hotmail.com (public contact)
2. Professor Tan Peng Chiong; tanpengchiong@yahoo.com
3. Associate Professor Vallikkannu Narayanan; valli2valli@gmail.com

Contact information

Type(s)
Public

Contact name
Dr Naumi Laboh

Contact details
Obstetric and Gynecology Department
University Malaya Medical Center
Lemba Pantai
Malaysia
59100

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
201882-6564

Study information

Scientific Title
Foley catheter vs Foley catheter and controlled-release dinoprostone insert labour induction in nulliparous women: a randomised trial

Acronym
FoleyCath-DinoprostoneCR Trial

Study objectives

Induction of labour with concurrent Foley catheter and controlled- release dinoprostone vaginal insert compared to standard Foley catheter shortens the induction to vagina delivery, therefore increasing patient satisfaction with the birth process.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Research Ethics Committee of University Malaya Medical center, 15/11/2018, NMRR ID: 44981

Study design
Interventional randomised controlled 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
Induction of labour in nulliparous women at term

Interventions
Randomisation will be completed using the Random.org random number generator in a random block of 4 or 8 by an investigator who is not involved in recruitment. The random allocation sequence will be placed in sealed numbered opaque envelopes for strict number order assignment to participants. Randomisation will therefore be opening the lowest remaining numbered sealed envelope. Participants will be randomised to receive treatment with the Foley catheter only, or treatment with a Foley catheter and a 10 mg controlled-release dinoprostone insert.
The time of the induction start will be recorded. Post initiation of induction, all participants will have cardiotocography (CTG) monitoring for at least 20 minutes, or until the fetus status is reassuring and thereafter at least every 6 hours. At 6 hours after the insertion of induction agent, patient pain score will be evaluated on a numerical pain rating scale.
The Foley catheter will be removed if any of the following occur:
1. Expulsion
2. Abnormal CTG
3. Spontaneous rupture of membrane
4. Uterine tachysystole (more than 5 contraction per 10 minutes over a 30 minute period) or uterine hyperstimulation syndrome
If none of these occur, it will be removed 24 hours after placement.

The controlled release Dinoprostone insert will be removed immediately in the following circumstances:
1. Onset of labour
2. Spontaneous rupture of the membrane or at the time before doing artificial rupture of membranes
3. Uterine tarcysystole or hyperstimulation syndrome
4. Abnormal CTG
5. Maternal systemic adverse dinoprostone effect such as nausea, vomiting, hypotension or tarchycardia
If none of these occur, it will be removed 24 hours after placement.
The time of Foley catheter and controlled-release Dinoprostone vagina insert removal and Bishop Score after removal will be recorded.
Amniotomy will be performed when the cervix dilatation is at least 2-3 cm with the fetal head stationed at or lower than -2. The time of amniotomy or spontaneous ruptured of membrane (SROM) will be recorded)
Oxytocin titration will be initiated as per standard care and the time of oxytocin commencement will be recorded.
For patients not achieving a favourable cervix stage or at least 2 cm of cervical dilatation, subsequent labour management will be at the discretion of the attending physician.
The time and mode of delivery, including the indication if operative delivery is done, will be recorded.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Controlled-release dinoprostone vaginal insert

Primary outcome measure
1. Interval between the start of induction and vaginal delivery as recorded in patient medical records
2. Maternal satisfaction with the birth experience from induction of labour to delivery assessed using
a numerical rating scale. A Likert scale will be used to determine whether the patient would recommend the method they had for induction of labour to a friend who needs to undergo induction of labour. This assessment will be done as soon as practicable after delivery.

Secondary outcome measures
Maternal:
1. Pain at 6 hours after start of induction assessed using a pain score scale (numerical rating scale 0 to 10)
2. Mode of delivery. This information will be taken from patient medical records as soon as possible before patient discharge from hospital.
3. Amniotomy. This information will be taken from patient medical records as soon as possible before patient discharge from hospital.
4. Intrapartum Oxytocin (excluding third stage use). This information will be taken from patient

medical records as soon as possible before patient discharge from hospital.
5. Delivery blood loss. This information will be taken from patient medical records as soon as possible before patient discharge from hospital.

Neonatal:
6. Apgar score at 5 minutes after birth. This information will be taken from patient medical records as soon as possible before patient discharge from hospital.
7. Umbilical cord arterial pH at birth. This information will be taken from patient medical records as soon as possible before patient discharge from hospital.
8. Admission to neonatal intensive care unit at birth and reason for admission. This information will be taken from patient medical records as soon as possible before patient discharge from hospital.

Overall study start date
01/02/2018

Completion date
01/10/2019

Eligibility

Key inclusion criteria
1. Nulliparous women (no previous pregnancy beyond 20 weeks of gestation)
2. Unfavourable cervix (Bishop score ≤5)
3. Aged 18 years or older
4. ≥37 weeks of gestation at enrolment
5. Singleton birth
6. Cephalic presentation
7. Membrane intact
8. Normal pre-induction CTG (cardiotocography)
9. Contraction not more than 2:10

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
206

Total final enrolment
206

Key exclusion criteria
1. Gross fetal anomaly
2. Allergy to latex or dinoprostone

Date of first enrolment
11/12/2018

Date of final enrolment
01/09/2019

Locations

Countries of recruitment
Malaysia

Study participating centre
University Malaya Medical Center
Lembah pantai, kuala lumpur
Malaysia
59100

Sponsor information

Organisation
Obstetric and gynecology department , UMMC

Sponsor details
university malaya medical center
59100 kuala lumpur
Malaysia
Lembah Pantai

Sponsor type
University/education

ROR
https://ror.org/00vkrxq08

Funder(s)

Funder type
University/education

Funder Name
Obstetric and gynecology department , UMMC

Results and Publications

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

Intention to publish date
31/08/2020

Individual participant data (IPD) sharing plan
The data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version v1	17/07/2018	03/12/2018	No	Yes
Results article		09/01/2022	10/01/2022	Yes	No