ISRCTN90853814 https://doi.org/10.1186/ISRCTN90853814

Comparing two different interventions after balloon catheter induction of labour in women who have not delivered a child before

Submission date
12/08/2020

Recruitment status
No longer recruiting

Registration date
13/08/2020

Overall study status
Completed

Last Edited
09/11/2023

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Currently, labour is induced in at least a third of all pregnancies. This process can be lengthy in a woman who has never delivered a child before. Starting labour with a Foley balloon is suitable for these women as it can slowly lead to opening of the cervix. After placing and filling up the Foley balloon in the lower womb, these women are safely sent home as it does not cause labour pains and it is unlikely for them to deliver at home without the breaking of waters and a hormone drip to initiate labour pains. The aim of this study is to compare two different interventions after balloon catheter induction of labour in women who have not delivered a child before.

Who can participate?
Pregnant women who have not delivered a child before, aged 18 and over, who are carrying a single, live unborn child at or beyond 37 weeks of pregnancy and who are planned for induction of labour.

What does the study involve?
After sending them home with the Foley balloon in place, participants will be randomly assigned to two groups. The researchers are trying to study the approach when the Foley balloon slips out of the vagina and its effect on the labour duration (from breaking of waters to delivery) and mothers' satisfaction with their birth process. Participants in Group A will be asked to return to the hospital the next morning and those in Group B will be asked to return immediately when the balloon drops. All participants will be asked to return immediately to the hospital if any of these happens at home: breaking of waters, bleeding from the vagina, pain or increased discomfort, decreased fetal movements, painful labour pains (two or more contractions in 10 minutes), fever (temperature 38°C or over) and inability to pass urine. When participants are admitted to the hospital as instructed, the cervical opening will be checked followed by the standard care provided by the hospital, which usually involves breaking the waters and starting a hormone drip to start labour pains.

What are the possible benefits and risks of participating?
Participants may or may not benefit from this study as it is not known if the above actions have a positive effect on the labour duration, but participants may be satisfied with their birthing process occurring at more safe hours (daytime). During the Foley balloon placement and filling, there may be some pain or discomfort and sometimes light vaginal bleed which settles. Rarely, there is difficulty in passing urine with the Foley balloon in place.

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

When is the study starting and how long is it expected to run for?
September 2020 to August 2021

Who is funding the study?
University Malaya Medical Centre (UMMC) (Malaysia)

Who is the main contact?
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Scientific

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Additional identifiers

Protocol serial number
2020621-8783

Study information

Scientific Title
A randomized controlled trial of two different regimens of outpatient Foley catheter induction of labour in nulliparous women

Study objectives
1. In the group that returns the following morning after Foley balloon expulsion, it is hypothesized that maternal satisfaction is improved on labour and delivery during daytime hours.
2. Duration of active labour, defined as amniotomy and oxytocin to delivery interval, would be non-inferior between the two groups; with a margin of 2 hours in the continued expectant management at home following balloon expulsion.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/08/2020, Medical Research Ethics Committee, University Malaya Medical Centre (Lembah Pantai, 59100, Kuala Lumpur, Malaysia; +60 (0)379493209; ummc@ummc.edu.my), ref: 2020621-8783

Primary study design
Interventional

Study design
Randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Outpatient Foley catheter induction of labour in nulliparous women

Interventions
All nulliparous women planned for induction of labour by the care provider will be assessed for eligibility and will be counselled regarding this study in the clinic and antenatal ward setting. If the women agree to participate in the study, informed consent will be obtained, and the patient information sheet will be handed to them.

On the scheduled date of induction, consented women will present themselves to the antenatal ward for an initial assessment including Bishop scoring and pre-induction fetal cardiotocography

(CTG). If these patients Bishop score and or CTG are not met within the inclusion criteria, they are excluded from the study.

Women will be positioned in the dorsal position. A Foley catheter size 16F is then introduced through the external os using either digital or speculum method (at the discretion of introducer). Once the tip of the catheter has passed the internal os by 4 to 5 cm, the balloon will be inflated with 60 ml of water and retracted so the balloon rests on the internal cervical os. The other end of the Foley catheter will be taped without tension to the medial aspect of the women's thigh. Fetal monitoring will be performed immediately after the inflation of the balloon catheter.

Once the catheter is in-situ and the post Foley catheter insertion CTG is normal, only then randomisation will be carried out. Randomisation is done by opening a sealed opaque and numbered envelope with the lowest available envelope assigned in strict order. Randomisation will be done using a random number generator at Random.org in random blocks of 4 or 8 sequence, generated by an investigator who is not involved in recruitment. Blinding is not possible due to the nature of the intervention.

Women randomised to either group will be allowed home upon a normal CTG tracing. Group A will be asked to wait expectantly at home after balloon expulsion and return to the hospital the next morning and those randomised to Group B will be asked to return immediately to the hospital upon balloon expulsion.

Women randomised either group will be given a written document with all the information that should bring them back to the hospital; such as: leaking of amniotic fluid, per vaginal bleeding, pain or severe discomfort, decreased fetal movements, painful contractility (≥2 contractions in 10minutes), fever (T ≥ 38°C) and inability to pass urine.

Upon re-admission to hospital, Foley catheter will be removed in both groups, and patients are subjected for amniotomy and oxytocin augmentation and managed according to the care provider practice.

Failed induction is diagnosed if Bishop score is ≤ 5 after removal of the catheter. The patient will then be assessed and counselled again by care provider for medical induction of labour or caesarean section.

Standard care will be provided to all women in the trial of labour induction, intrapartum and postpartum care. Care providers always have full discretion in deciding for patients' best interest.

Maternal satisfaction scores during the induction process will be assessed after delivery using the visual numerical rating scale and scored from 0-10. Data will be collected as per the case report form.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Foley catheter

Primary outcome(s)
1. Maternal satisfaction evaluated using a visual numerical scale scored 0-10, assessed within 24 hours of delivery
2. Duration of active labour, defined as amniotomy and oxytocin to delivery interval, measured in hr:min; obtained from patient's medical records at birth

Key secondary outcome(s)
Maternal outcome measures:
1. Induction to delivery interval (duration measured in hr:min), obtained from patient's medical records at birth
2. Mechanism of membrane rupture (amniotomy or spontaneous rupture of membrane), obtained from patient's medical records at birth
3. Oxytocin augmentation (duration measured in hr:min), obtained from patient's medical records at birth
4. Use of additional method(s) of cervical ripening, obtained from patient's medical records at birth
5. Use of regional analgesia in labour, obtained from patient's medical records at birth
6. Mode of delivery, obtained from patient's medical records at birth
7. Estimated blood loss, obtained from patient's medical records at birth
8. Fever; one or more readings of temperature ≥ 38°C, diagnosis of chorioamnionitis or endometritis, obtained from patient's medical records intrapartum and day 1 postpartum
9. Total duration of hospital stay, obtained from patient's medical records on discharge
10. Date and time of catheter removal/dislodged, obtained from patient's medical records upon admission to hospital

Neonatal outcome measures:
1. Apgar score at 1 and 5 minutes measured using the Apgar score chart at 1 and 5 minutes of birth
2. Arterial cord pH: blood drawn into a heparinized syringe taken from the umbilical artery of the umbilical cord after delivery of the baby, measured using a blood gas machine located in the labour ward at time of birth
3. Birth weight measured using a calibrated digital weighing scale located in the labour ward nursery at birth
4. Neonatal admission, taken from the medical records of the baby at birth or before mother's date of hospital discharge

Completion date
31/12/2021

Eligibility

Key inclusion criteria
1. Nulliparous
2. Age 18 years and above
3. Gestational age of ≥ 37weeks at enrolment
4. Scheduled induction of labour
5. Viable pregnancy
6. Cephalic presentation
7. Singleton pregnancy
8. Unfavourable cervix (Bishop score ≤ 5)

9. Absence of significant contraction ≥ 2 in 10 minutes
10. Intact membranes
11. Reassuring pre induction fetal cardiotocography (CTG)
12. Patient has motor vehicle
13. Patient stays about 30 minutes distance from University Malaya Medical Centre

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Female

Total final enrolment
330

Key exclusion criteria
1. Allergic to latex
2. Multiparous
3. Women with ruptured membranes
4. Contraindication to vaginal delivery
5. Known gross fetal anomaly
6. Fetal weight clinically estimated to be ≤ 2 kg and ≥ 4 kg and confirmed by ultrasound
7. Previous uterine scar (caesarean/myomectomy)

Date of first enrolment
01/09/2020

Date of final enrolment
31/12/2021

Locations

Countries of recruitment
Malaysia

Study participating centre
University Malaya Medical Centre
Jalan Universiti

Kuala Lumpur
Malaysia
59100

Sponsor information

Organisation
University Malaya Medical Centre

ROR
https://ror.org/00vkrxq08

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Malaya Medical Centre

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Sreella Raghavan (rsreella@ummc.edu.my) and Prof. Tan Peng Chiong (pctan@um.edu.my).

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		16/10/2023	09/11/2023	Yes	No