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Induction of labour with a foley catheter in pregnant women with previous successful vaginal birth in outpatient vs inpatient settings

Submission date
18/12/2018

Recruitment status
No longer recruiting

Registration date
11/01/2019

Overall study status
Completed

Last Edited
01/09/2021

Condition category
Pregnancy and Childbirth

[X] Prospectively registered

[X] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
Labour is a natural process which usually starts on its own leading to birth. Labour may need to be started artificially for the advantage of the baby, mother or occasionally for convenience; this process is called induction of labor.

The method of induction of labour depends primarily on the condition or “ripeness” of the cervix. A ripe cervix is typically slightly open, short and soft. With a ripe cervix, labour is usually induced by rupturing the forewaters through the sufficiently opened (at least 2-3 cm open) cervix and the starting a hormone (oxytocin) intravenous drip to initiate contractions. If the cervix is unripe, mechanical method like inserting a Foley catheter (a tube with a inflatable balloon at one end) through the cervix and inflating the balloon to 60 ml with saline is often used to ripen the cervix. The balloon exerts pressure on the internal opening of the cervix typically painless, causing the cervix to slowly (over up to 24 hours) open to 3-4 cm at which point, the balloon may fall out and the forewaters can then be readily ruptured and oxytocin drip started to initiate contractions and active labour.

Cervical ripening and labour induction is usually faster in women who had previously had normal birth, with ripening expected to be achieved within 12 hours with the Foley balloon and delivery expected after 6-8 hours of rupturing membranes and commencing the oxytocin drip. These induction process interval timings permit the logical time structuring of labour induction in order to increase safety and patient acceptability.

As the Foley catheter balloon ripening of the cervix is typically painless and does not initiate contraction pains by itself, it is potentially an ideal method to be applied on an overnight-outpatient basis as the woman can be expected to be able to sleep through the ripening process.

We plan to insert the Foley catheter at 8pm and then for women to be randomly allocated to 1) discharge home to return to hospital for assessment (and probable rupturing of forewaters and

oxytocin drip) at 8 am the following morning unless interim clinical concerns (but not for straightforward balloon expulsion) or 2) remain in hospital and if balloon expelled in the interim before 8 am, for rupturing of forewaters and oxytocin drip to expedite labour and birth.

We hypothesized that allowing discharge home overnight after Foley catheter insertion in women who had previously given birth vaginally but who have unripe cervixes to start with compared to in-hospital management throughout will allow 1) a greater proportion to give birth during working hours when care provisions are best resourced and 2) for their labour to occur through controlled and civilised hours which should increase satisfaction with the labour induction process.

Who can participate?
Women aged over 18 years at term with previous successful vaginal delivery beyond 28 weeks with 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 outpatient group will be allowed to go back home after electronic fetal monitoring is normal. While those who are randomised to inpatient group will be managed according to the hospital protocol.
The Foley catheter will be removed after 12 hours unless they have already been expelled or removed earlier for medical reasons. After device removal at 12 hours, participants will receive standard labour care as decided with their care provider in accordance to patient wish. If the cervix is still unripe and the baby and mother are in good condition, additional attempts to ripen the cervix might be considered.

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?
Benefits:
It is not known which method have better outcome or outcome maybe similar. If you are randomised to the superior method, you may be more satisfied and the time spend in the hospital may be less.

Risks:
The risks associated with foley catheter induction of labor are minimal.

Where is the study run from?
University Malaya Medical Centre

When is the study starting and how long is it expected to run for?
You will involve with this study from the initiation of labour induction until your delivery.
This study expected to start in Jan 2019 till Dec 2019

Who is funding the study?
Obstetric and Gynaecology Department, University Malaya Medical Centre

Who is the main contact?
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
2018927-6722

Study information

Scientific Title
Outpatient vs inpatient Foley catheter induction of labour in multiparous women: a randomised trial

Acronym
OVIFIOL

Study objectives
Outpatient induction of labour with Foley catheter in a parous woman with an unfavourable cervix will be more acceptable and convenient. This may improve maternal satisfaction with the induction process. It is also hypothesised that it will also shorten the total duration of hospital stay and result in more delivery during the normal working hours (8am to 5pm)

Ethics approval required
Old ethics approval format

Ethics approval(s)
University Malaya Medical Research Ethics Committee (UMMC-MREC), 22/10/2018

Study design
Single-centre randomised controlled trial with no blinding

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
Pregnant women who have previously successfully given birth vaginally and require induction of labor for specific reasons

Interventions
Randomisation will only be carried out once the catheter is in-situ and post foley catheter insertion CTG is normal. Randomisation is by the opening of sealed opaque and numbered

envelope with lowest available envelope assigned in strict order. Randomisation will be done using a random number generator at Random.org in random block of 4 or 8 sequence, generated by investigator who is not involved in recruitment. Blinding is not possible due to the nature of the intervention.

Patients will be randomised into the outpatient group or the inpatient group. For the outpatient group, patients will be given a written document with all the information that should bring them back to the hospital, such as: leaking of amniotic fluid or per vaginal bleeding; pain or severe discomfort; decreased fetal movements; painful contractility (>2contractions/10 min) and fever (T > 380C). They will be asked to come back the next day morning at 8am for removal of foley catheter.

Patients in the inpatient group were monitored and oriented in accordance to the Department's protocol. Foley catheter will be removed if spontaneous ruptured of membrane occurs, suspected fetal distress from CTG and or if it still present 12 hours after placement.

Failed induction is diagnosed when the Bishop score ≤ 5 after removal of catheter. If failed induction occurs, patient will be assessed and counseled again by care provider for medical induction of labor or caesarean section.

After removal of Foley catheter, amniotomy and oxytocin augmentation will be started and managed according to the care provider practice.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Maternal satisfaction with their care will be measured using the visual numerical rating scale (from 0-10) after delivery.
2. The percentage of women delivering during "working hours" (8am to 5pm).

Secondary outcome measures
Maternal outcomes will be determined using data retrieved from patients' case notes after delivery:
1. Intervention to delivery interval
2. Membrane rupture to delivery interval
3. Mechanism of membrane rupture
4. Oxytocin augmentation
5. Use of additional method(s) for cervical ripening
6. Use of regional analgesia in labour
7. Mode of delivery
8. Estimated blood loss
9. Fever single or more readings of temperature ≥38oC (intrapartum and day 1 postpartum), diagnosis of chorioamnionitis or endometritis
10. Duration of hospital stay
11. Date and time of catheter evacuated/expulsed

Neonatal outcomes will be determined using data retrieved from patients' case notes after delivery:
1. The physical condition of newborn infants will be measured using the Apgar score at 1 and 5 minutes.

2. Arterial cord pH
3. Birth weight
4. Neonatal admission

Overall study start date
01/08/2018

Completion date
31/01/2020

Eligibility

Key inclusion criteria
1. Aged 18 years and above
2. Gestational age of > 37 weeks at enrolment
3. Scheduled induction of labour
4. Viable pregnancy
5. Cephalic presentation
6. Singleton pregnancy
7. Unfavourable cervix (Bishop Score ≤ 5)
8. Intact membranes
9. Reassuring pre induction fetal cardiotocography (CTG)
Added 18/06/2019:
10. Must have their own transport and live within 30km of the hospital

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
159

Total final enrolment
163

Key exclusion criteria
1. Allergic to latex
2. Nulliparous
3. Previous uterine scar (caesarean/myomectomy)

Date of first enrolment
18/02/2019

Date of final enrolment
18/04/2020

Locations

Countries of recruitment
Malaysia

Study participating centre
University Malaya Medical Centre
Jalan Universiti
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Sponsor information

Organisation
University Malaya Medical Centre

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/00vkrxq08

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Malaya Medical Centre

Results and Publications

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

Intention to publish date
31/05/2020

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

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	21/12/2018	11/01/2019	No	Yes
Protocol file	version v1	21/12/2018	11/01/2019	No	No
Results article		30/08/2021	01/09/2021	Yes	No