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Does 8 hourly vaginal examination interval after amniotomy and cervical ripening with Foley's catheter in women with firstborn baby improve maternal satisfaction during labour?

Submission date
29/03/2021

Recruitment status
No longer recruiting

Registration date
08/05/2021

Overall study status
Completed

Last Edited
10/06/2025

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
Currently, the standard practice for vagina examination for all women undergoing labour is at 4 hourly interval. However, frequent routine vagina examination can lead to pain, embarrassment and discomfort to labouring women. Frequent routine practise of vaginal examination also was found not to influence duration of labour and can also cause infection to baby after delivery. This study aims to show that 8-hourly vaginal examination interval in pregnant women after cervical ripening with Foleys catheter and breaking of waterbag will improve women satisfaction

Who can participate?
Women aged 18 years or older, who are giving birth for the first time.

What does the study involve?
Using a random system, you would be randomly assigned into either Group 1 or Group 2 after your waterbag has been broken.
If you are in Group 1, the doctor involved will perform a vaginal examination on 8 hourly basis. If you are in Group 2, the doctor involved will perform a vaginal examination on 4 hourly basis as per standard care.
The doctor involved will record the duration of your labour, type of delivery you undergo, pain relieved used as per your demand and any problems that arises during labour and after delivery to both you and your baby
You will also be asked to rate your overall labour process satisfaction after your delivery
Both groups will have the same other medical procedure, examination, investigations, operation and care as of any other patients admitted for childbirth after induction with Foley’s balloon
You will receive other similar standard medical and childbirth care aside from the above-mentioned intervention

What are the possible benefits and risks of participating?
There may or may not be any benefits to you. Information obtained from this study will help

improve the treatment or management of other patients with the same disease or condition. There is no complication/side effect anticipated from the study. You will still receive the same standard medical and childbirth care as warranted by the clinical situation

Where is the study run from?
The Department of Obstetrics & Gynaecology, University of Malaya Medical Centre (Malaysia)

When is the study starting and how long is it expected to run for?
March 2021 to December 2022 (updated 09/06/2021, previously: May 2022)

Who is funding the study?
The Department of Obstetrics & Gynaecology, University of Malaya Medical Centre (Malaysia)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil Known

Protocol serial number
MECID Number 2021315-9962

Study information

Scientific Title
Randomised controlled trial of 4 hourly versus 8 hourly vaginal examination interval after amniotomy and cervical ripening with Foley's catheter in nulliparas

Study objectives
Eight hourly vaginal examination in nulliparous women after amniotomy and cervical ripening with foleys catheter will result in higher maternal satisfaction and comparable amniotomy to delivery interval versus 4-hourly vaginal examination

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/05/2021, University Malaya medical centre ethics committee (Lembah Pantai, 59100 Kuala Lumpur, Malaysia; +60 (0)3-79493209; no email provided), ref: 2021315-9962

Study design
Single centre interventional randomized controlled trial

Primary study design
Interventional

Study type(s)

Other

Health condition(s) or problem(s) studied
Maternal satisfaction with induction of labor

Interventions
All women who fulfilled the inclusion criteria undergoing induction via Foley catheter insertion are identified by health care providers at the delivery suite and antenatal ward. will be assessed for recruitment eligibility by going through their medical records when they attending their scheduled induction of labour in our obstetric unit. Participants who fulfilled the eligibility criteria will be provided with a patient information sheet and counselled for participation in this study. If women agree to participate, written and informed consent will be taken from participants.

Following removal of foley's catheter, manually or spontaneously, the vaginal examination will be performed and participants with cervical dilatation ≥ 3cm will be sent to labour ward for amniotomy. If participants fulfilled the final criteria; (i) cervical os dilatation of ≥ 3cm, (ii) cephalic presentation, (iii) station not higher than -2, (iv) reassuring fetal heart status, randomization will be performed post amniotomy. Titration of intravenous oxytocin augmentation is at the discretion of the care provider.

Randomization will be carried out by opening the lowest-numbered seal opaque envelope. Randomization for 1:1 ratio with blocks of 4 and 8 done by an investigator not involved in the recruitment process will be used to generate the randomization code. Participants will be randomized to either the intervention group (Group 1) or the control group (Group 2).

Participants in the intervention group will be subjected to 8 hourly routine vaginal examination while participants in the control group will be subjected to standard 4 hourly routine vaginal examination during labour. Participants on both groups will require additional vaginal examination as per standard care in the event of (i) administration of analgesia/epidural, (ii) fully dilated cervical os, or (iii) application of fetal scalp electrode. Labour progress will be documented in partograph. Fetal heart rate and uterine activity will be monitored continuously during the participants labor process.

Following delivery, participants will be asked about maternal satisfaction; "Please rate your satisfaction on your allocated care during your labor ". The score will be rated by both groups via the Visual Numerical Rating Scale (VNRS) with scoring from 0-10. Data will be collected as per the case report form. Detail pertaining to participant's delivery outcome will be retrieved from medical notes and will be included in the case report form

Intervention Type
Other

Primary outcome(s)
1. Maternal satisfaction of labour care measured using a Visual Numerical Rating Score (VNRS) from 0-10, assessed soon after delivery
2. Duration of active labour, defined as amniotomy to delivery interval is assessed from hospital records after hospital discharge

Key secondary outcome(s))
Current secondary outcome measures as of 09/06/2021:

Maternal outcomes:
1. Mode of delivery
2. Indication for caesarean and operative vaginal delivery
3. Oxytocin induction/augmentation in labour
4. Fever which is defined from as single temperature reading of 38°C or greater
4.1. Intrapartum
4.2. Post-partum
5. Analgesic & epidural used in labour
6. Estimated delivery blood loss
7. Uterine hyperactivity:
7.1. Tachysystole (six of more contractions in 10 minutes over two consecutive 10-minute periods)
7.2. Hypertonus (sustained contraction 2 min or longer)
7.3. Hypertonus with fetal heart rate abnormality
8. CTG abnormality based on NICE guideline
9. Duration of hospital stay from time of induction until discharge
*Indication for induction of labour have been removed from secondary outcome but the data will be captured and recorded in the data collection form

Neonatal outcomes:
1. Apgar score at 1 and 5 minutes
2. Umbilical cord arterial blood pH and base excess
3. Birth weight
4. Neonatal admission (NICU/Special care nursery/Indication for neonatal admission)

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Previous secondary outcome measures:

Measured using patient records after birth:
Maternal outcomes:
1. Caesarean section rate & Indication for caesarean section
2. Operative vagina delivery Indication
3. Oxytocin induction/augmentation in labour
4. Fever which is defined from as single temperature reading of 38°C or greater
5. Analgesic & epidural used in labour
6. Estimated delivery blood loss
7. Uterine hyperactivity:
7.1. Tachysystole (six of more contractions in 10 minutes over two consecutive 10-minute periods)
7.2. Hypertonus (sustained contraction 2 min or longer)
7.3. Hypertonus with fetal heart rate abnormality
8. CTG abnormality based on NICE guideline
9. Duration of hospital stay from time of induction until discharge
10. Indication for induction of labour

Neonatal outcomes:
1. Apgar score at 1 and 5 minutes
2. Umbilical cord arterial blood pH and base excess
3. Birth weight
4. Neonatal admission (NICU/Special care nursery/Indication for neonatal admission)

Completion date
31/12/2022

Eligibility

Key inclusion criteria
1. Women who had cervical ripening with Foley catheter only and favourable cervix with cervical dilatation of 3cm or greater (suitable for amniotomy) with contraction <1:5min
2. Nulliparous
3. No prior pregnancy beyond 20 weeks gestation
4. Age 18 years and above
5. Gestational age of ≥37weeks at enrolment scheduled induction of labour
6. Scheduled induction of labour
7. Viable pregnancy
8. Cephalic presentation
9. Singleton pregnancy
10. Reassuring pre induction fetal cardiotocography (CTG)
11. Intact membrane

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Key exclusion criteria
1. Contraindication to vaginal delivery
2. Known gross fetal anomaly
3. Fetal weight clinically estimated to be ≤2 kg & ≥4kg and confirmed by ultrasound
4. Previous uterine surgery, ie: myomectomy, hysterotomy and history of iatrogenic uterine perforation

Date of first enrolment
10/05/2021

Date of final enrolment
30/04/2022

Locations

Countries of recruitment

Malaysia

Study participating centre
Kompleks Wanita dan Kanak Kanak, Pusat Perubatan Universiti Malaya
Lembah Pantai
Kuala Lumpur
Malaysia
59200

Sponsor information

Organisation
University Malaya Medical Centre

ROR
https://ror.org/00vkrxq08

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be 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?
Results article		02/10/2024	10/06/2025	Yes	No
Participant information sheet	version v1.1	01/05/2021	01/06/2021	No	Yes
Participant information sheet	Participant information sheet version v2.0	11/11/2025	11/11/2025	No	Yes

Protocol file	01/03/2021	01/06/2021	No	No