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Vaginal examination performed routinely at 8 hours or at 4 hours after starting the oxytocin drip to augment the labour of women delivering their first child

Submission date
18/10/2023

Recruitment status
No longer recruiting

Registration date
03/11/2023

Overall study status
Completed

Last Edited
01/11/2023

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 augmentation, usually with the oxytocin drip, varies from 0.7% to 97.0% globally, exceeding 30% in 14 countries, reflecting diversity in practice and individual circumstances. The aim of augmentation is to achieve a contraction frequency of 4 in 10 minutes to speed up labour and delivery.
Recent data has shown that progress in early labour (before 6 cm of opening) can be slow. Labour may take more than 6 hours to progress from 4 to 5 cm of dilation and more than 3 hours to progress from 5 to 6 cm of dilation.
Labour will continue to progress to delivery regardless of whether a vaginal examination is performed or not. Vaginal examination is also not needed to control the oxytocin drip rate during augmentation to optimise contraction frequency. This role is taken on by electronic fetal monitoring with the cardiotocograph which also monitors the baby's condition.
Many women expressed that vaginal examination during their labour is painful and an invasion of privacy.
However, labour that is very prolonged (usually by 1 or 2 days) is strongly associated with adverse outcomes and it makes sense to periodically assess progress. There is very limited data to guide practice on the best frequency of vaginal examination to assess labour progress, especially in the early stage of labour before 6 cm of cervical opening.
The aim of this study is to evaluate if a routine examination at 8 hours instead of 4 hours will improve maternal satisfaction with the intervention (by reducing overall vaginal examination) but will not prolong the time it takes for the baby to be delivered.

Who can participate?
Women aged 18 years and over who are delivering their first child and need oxytocin augmentation in early spontaneous labour

What does the study involve?
Participants are randomly allocated to one of two different frequencies of vaginal examination to assess labour routinely at 8 hours or at 4 hours.

What are the possible benefits and risks of participating?
Maternal satisfaction with labour monitoring may increase with less frequent vaginal assessment. The time taken to birth might lengthen with less frequent vaginal assessment. As clinically indicated vaginal examination (for example to diagnose imminent delivery) can be performed without limitation, the researchers do not expect any major benefits or harms.

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 2023 to December 2024

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

Who is the main contact?
1. Dr Li Kong Wei, likongwei@ummc.edu.my
2. Prof. Dr Tan Peng Chiong, pctan@um.edu.my

Contact information

Type(s)
Principal investigator

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Additional identifiers

Protocol serial number
2023622-12588

Study information

Scientific Title
Vaginal examination at 8 hours compared to 4 hours after commencement of oxytocin augmentation in nulliparous women: a randomized controlled trial

Study objectives
It is hypothesised that vaginal assessment at 8 hours compared to 4 hours will not prolong the intervention to delivery interval (non-inferiority hypothesis) and will increase maternal satisfaction (superiority hypothesis).

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 27/09/2023, University of Malaya Medical Centre Medical Research Ethics Committee (Lembah Pantai, Kuala Lumpur, 59100, Malaysia; +60 (0)379498473; ummc-mrec@ummc.edu.my), ref: MREC ID : 2023622-12588

Primary study design
Interventional

Study design
Single-centre parallel-design randomized control trial

Study type(s)
Other

Health condition(s) or problem(s) studied
Oxytocin augmentation of labour

Interventions
Randomization is done by opening the lowest number, sealed and opaque envelope that is available. The randomization sequence will be generated using a random number generator in random blocks of 4 or 8 by an investigator who is not involved in recruitment. Participants would be randomized into two trial arms:

1. Routine vaginal examination 4 hours after the last vaginal examination
2. Routine vaginal examination 8 hours after the last vaginal examination

Intervention Type

Procedure/Surgery

Primary outcome(s)
1. Augmentation to delivery interval measured after delivery, calculated from the recorded date and time of the start of oxytocin augmentation and date and time of birth, variable will be in hours.
2. Maternal satisfaction with the allocated vaginal examination regimen, obtained as soon as possible on the postnatal ward and before their discharge, participants will be asked:
2.1. To rate using an 11-point (0-10) (visual numerical rating scale - VNRS) their satisfaction with the allocated intervention of vaginal examination at 4 or 8 hours
2.2. To provide a response using a 5-grade Likert scale on if they will recommend their allocated intervention of vaginal examination at 4 or 8 hours to a friend, graded from strongly agree, agree, neither agree nor disagree, disagree to strongly disagree

Key secondary outcome(s)
Recorded directly onto the case report form. Information not in the case report form will be acquired from hospital charts or notes.

Maternal outcomes assessed at birth:
1. Mode of delivery (spontaneous vaginal, vacuum, forceps and caesarean) and indication of operative delivery (vacuum, forceps and caesarean)
2. Epidural analgesia
3. Estimated delivery blood loss
4. Fever with temperature ≥38°C or greater (intrapartum to hospital discharge)
5. Maternal recommendation of allocated intervention to a friend (5-point Likert scale)
6. Maternal ICU admission
7. Hysterectomy
8. Relaparotomy
9. Vaginal examination as scheduled
10. Interim vaginal examination (and indication)
11. Number of vaginal examinations during the study period (to delivery)
12. Time (from index vaginal examination at recruitment) to
13. First subsequent vaginal examination
14. Diagnosis of second stage
15. Birth
16. Hospital discharge

Neonatal outcomes assessed at birth:
1. Apgar score at 1 and 5 minutes
2. Birth weight
3. Neonatal admission (and indication)
4. Cord pH
5. Birth trauma (specify)
6. Hypoxic ischaemic encephalopathy/need for therapeutic hypothermia

Completion date
01/12/2024

Eligibility

Key inclusion criteria

1. Spontaneous labour
2. Nulliparous (no prior pregnancy >22 weeks)
3. Singleton pregnancy
4. Gestational age of ≥37 weeks
5. 18 years old and above
6. Cervical dilatation at <6 cm
7. Oxytocin augmentation for labour delay actioned and started

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Female

Key exclusion criteria
1. Abnormal fetal heart rate tracing
2. Previous uterine trauma (myomectomy, hysterotomy, perforation)
3. Major fetal malformation
4. Meconium staining of liquor
5. Chorioamnionitis
6. Severe preeclampsia
7. Non-reassuring maternal status
8. Contraindication for vaginal delivery

Date of first enrolment
30/12/2023

Date of final enrolment
30/11/2024

Locations

Countries of recruitment
Malaysia

Study participating centre
University Malaya Medical Centre
Lembah Pantai

Kuala Lumpur
Malaysia
51000

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 raw data generated during and/or analyzed during the current study are/will be available upon request from Dr Li Kong Wei (likongwei@ummc.edu.my) subject to institutional review board approval 6 months after publication.
The type of data that will be shared: the reported data
Whether consent from participants was required and obtained: yes
Comments on data anonymization: yes
Any ethical or legal restrictions: Data sharing will be subject to ethical review and approval

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			24/10/2023	No	Yes
Protocol file			24/10/2023	No	No