

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	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 03/11/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 01/11/2023	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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

Clinical Trials Information System (CTIS)

Nil known

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

Study design

Single-centre parallel-design randomized control trial

Primary study design

Interventional

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 $\geq 38^{\circ}\text{C}$ 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