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Routine vaginal examination after 4 compared to 8 hours following diagnosis of early spontaneous labour in women who have previously given birth

Submission date
10/10/2023

Recruitment status
No longer recruiting

Registration date
18/10/2023

Overall study status
Completed

Last Edited
17/01/2025

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Vaginal examination is the most used to monitor progress in labour. Good evidence of effectiveness for this form of monitoring labour progress is scarce, considering the sensitivity of the procedure for many women receiving it, and the potential for adverse response. Digital vaginal examination at intervals of four hours is commonly recommended in the first stage of labour even in low-risk women with extremely scarce evidence this frequency is superior. Some data is available that routine vaginal examination in labour every 2 compared to 4 hours is not helpful.
Normal labour may take more than 6 hours to progress from 4 to 5 cm and more than 3 hours to progress from 5 to 6 cm of dilation. Women with experience of childbirth and those expecting their first child appeared to progress at a similar pace before 6 cm. However, after 6 cm labour is faster in women with vaginal birth experience. Women with a good history of uneventful prior vaginal birth usually do not require medical treatment in their spontaneous labour as their labour is expected to be straightforward and labour will naturally continue to progress to delivery without interim assessment for them. Hence delaying the first routine examination after diagnosis of early labour may help many such women to avoid a non-contributory vaginal examination. As needed (non-routine) vaginal examination is permitted at any time e.g., because the women have the urge to push suggesting the baby is close to delivery.
The objective of this study is to evaluate 4 hours compared to 8 hours routine vaginal assessment after diagnosis of early labour on whether there will be any delay to delivery and if women assigned to 8 hour assessment will express higher satisfaction in anticipation that the number of vaginal examinations during labour will be minimised.

Who can participate?
Multiparous women aged 18 years old with no previous scar at term in early spontaneous labour

What does the study involve?
Eligible participants will be selected and a baseline vaginal examination is done prior enter to

labour suite. Then participants will be randomly assigned to one of the two interventions, with an equal chance of being assigned to either group i.e., vaginal examination at A) 4 hours or B) 8 hours from the last vaginal examination in the labour suite.
During the trial intervention period, management is reactive to clinical developments that warrant requisite actions.

What are the possible benefits and risks of participating?
Different time of vaginal examination does not impact the time of delivery. Apart from the time to birth, the study is not anticipated to have an effect on other mother or baby outcomes. Major adverse outcomes arising from the trial interventions are not anticipated. Less vaginal examination helps to improve maternal satisfaction towards the delivery process and it helps to reduce unnecessary interventions such as oxytocin augmentation, caesarean section and instrumental delivery.

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?
June 2023 to February 2025

Who is funding the study?
Department of Obstetrics and Gynaecology, Faculty of Medicine, University Malaya, Malaysia

Who is the main contact?
1. Dr Nor Izzati binti Mohd Radzali, izzati.radzali@ummc.edu.my
2. Prof. Dr Tan Peng Chiong, pctan@um.edu.my

Contact information

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
202368-12550

Study information

Scientific Title
Routine vaginal examination at 4 vs 8 hours in multiparous women in early spontaneous labour: a randomised controlled trial

Study objectives
Routine vaginal assessment after 8 hours compared to 4 hours will not prolong the interval to delivery (non-inferiority hypothesis) and may increase maternal satisfaction on the allocated vaginal examination regimen during labour (superiority hypothesis)

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 05/10/2023, 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: 202368-12550

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Parallel group

Study setting(s)

Hospital

Study type(s)
Other

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Spontaneous labour

Interventions
Participants are randomly assigned to arms using sealed envelope.

A. Routine vaginal examination 4 hours after the last vaginal examination
B. Routine vaginal examination 8 hours after the last vaginal examination

Interim vaginal examination can be performed at any time as deemed clinically indicated by the care provider (including non-reassuring fetal status, severe maternal distress, suspicion of second stage or imminent delivery, meconium staining of the liquor etc). The unscheduled examination will be recorded. Vaginal examination frequency following an interim or the scheduled routine examination will revert to the care provider's usual practice and recorded

Intervention Type
Other

Primary outcome measure
1. Last vaginal examination before randomization to delivery interval (hours) measured using patient records at the end of the study
2. Maternal satisfaction with the allocated vaginal examination regimen in labour measured as soon as possible on the postnatal ward and before their discharge:
2.1. Rate using a 11-point Visual Numerical Scale their satisfaction with allocated intervention of vaginal examination at 4 or 8 hours
2.2. 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

Secondary outcome measures
Maternal outcomes measured using patient records at the end of the study:
1. Mode of delivery (spontaneous vaginal, vacuum, forceps and caesarean) and indication of operative delivery (vacuum, forceps and caesarean)
2. Epidural analgesia in labour
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
11. Number of vaginal examinations during study period (randomisation to delivery)
12. Time (from index vaginal examination at recruitment) to

12.1. First subsequent vaginal examination
12.2. Second stage

Neonatal outcomes measured using patient records at the end of the study:
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

Overall study start date
01/06/2023

Completion date
01/02/2025

Eligibility

Key inclusion criteria
1. Multiparous women (at least one vaginal birth ≥24 weeks)
2. Spontaneous labour
2.1. Cervical dilatation 3-5 cm
2.2. Painful contractions ≥3 in 10 minutes
3. As soon as possible after last vaginal examination (within two hours)
4. Reassuring fetal cardiotocography (CTG)
5. Singleton pregnancy
6. Cephalic presentation
7. Gestational age of ≥ 37 weeks
8. 18 years old and above

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
254

Key exclusion criteria
1. Previous uterine trauma (caesarean, myomectomy, perforation)
2. Major fetal malformation
3. Chorioamnionitis

4. Severe preeclampsia
5. Non-reassuring maternal status
6. Contraindication for vaginal delivery

Date of first enrolment
21/10/2023

Date of final enrolment
09/10/2024

Locations

Countries of recruitment
Malaysia

Study participating centre
University Malaya Medical Centre
Lembah Pantai
Kuala Lumpur
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Sponsor information

Organisation
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Sponsor type
University/education

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ROR
https://ror.org/00vkrxq08

Funder(s)

Funder type
University/education

Funder Name
Universiti Malaya

Alternative Name(s)
University of Malaya, University Malaya, Malayan University, UM

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Malaysia

Results and Publications

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

Intention to publish date
01/05/2025

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 Nor Izzati (izzati.radzali@ummc.edu.my) 12 months after publication subject to institutional review board approval

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 1	19/06/2023	13/10/2023	No	Yes
Protocol file			13/10/2023	No	No