

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

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<b>Registration date</b> 18/10/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 17/01/2025	<b>Condition category</b> 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

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](mailto:izzati.radzali@ummc.edu.my)

2. Prof. Dr Tan Peng Chiong, [pctan@um.edu.my](mailto:pctan@um.edu.my)

## Contact information

### Type(s)

Principal investigator

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## Additional identifiers

### Protocol serial number

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

### Study type(s)

Other

### 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(s)**

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

## **Key secondary outcome(s)**

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

## **Completion date**

01/02/2025

## **Eligibility**

### **Key inclusion criteria**

1. Multiparous women (at least one vaginal birth  $\geq 24$  weeks)
2. Spontaneous labour
  - 2.1. Cervical dilatation 3-5 cm
  - 2.2. Painful contractions  $\geq 3$  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  $\geq 37$  weeks
8. 18 years old and above

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

Female

**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

Malaysia  
51000

## Sponsor information

### Organisation

University Malaya Medical Centre

### 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, King Edward VII College of Medicine, Raffles College, University of Malaya in Singapore, , , , UM

### Funding Body Type

Government organisation

### Funding Body Subtype

Universities (academic only)

### Location

Malaysia

## 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 Nor Izzati ([izzati.radzali@ummc.edu.my](mailto: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?
<a href="#">Participant information sheet</a>	version 1	19/06/2023	13/10/2023	No	Yes
<a href="#">Protocol file</a>			13/10/2023	No	No