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Internal examination in women with previous delivery during labour

Submission date
04/10/2021

Recruitment status
No longer recruiting

Registration date
07/10/2021

Overall study status
Completed

Last Edited
05/11/2024

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
Pregnant women report physical and psychological pain related to internal (vaginal) examinations. The aim of this study is to find out whether changing the interval of internal examinations can improve women's satisfaction with their treatment.

Who can participate?
Women aged more than 18 years old who have experienced delivery before and are planned for early delivery before the onset of spontaneous labour.

What does the study involve?
Participants will be randomly assigned to two groups: one group for internal examinations at a 4-hour interval and another group for internal examinations at an 8-hour interval. The outcome of their labour will be recorded.

What are the possible benefits and risks of participating?
This study may help improve the management of labour in the future. Women may receive fewer internal examinations.

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 2021 to October 2022

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

Who is the main contact?
Dr Aishah Binti Mohd
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Contact information

Type(s)
Scientific

Contact name
Dr Aishah Mohd

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
4

Study information

Scientific Title
Randomised controlled trial of 4 hours versus 8 hours vaginal examination intervals after amniotomy and cervical ripening with Foleys catheter in multiparous women

Study objectives
Women in the 8-hour vaginal examination interval group are more satisfied with the labour process. It is also hypothesized that the rate of delivery will be the same among the two groups.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 07/09/2021, Medical Research Ethics Committee, University Malaya Medical Centre (Medical Research Ethics Committee, University Malaya Medical Centre, Lembah Pantai, 59100, Kuala Lumpur, Malaysia; +60 (0)379493209/+60 (0)379492251), ref: 202159-10127

Study design
Prospective randomized control trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Multiparous women after induction with Foleys catheter and amniotomy induction of labour

Interventions
All potential candidates for planned induction of labour who fulfil the inclusion criteria are identified by health care providers at the delivery suite and antenatal ward. Potential candidates will be assessed for recruitment eligibility by using the Eligibility Form. Potential candidates who fulfil the eligible criteria will be provided with a patient information sheet. If potential candidates agree to participate, written and informed consent will be taken.

Following removal of Foleys catheter, manually or spontaneously, a vaginal examination will be performed and participants with cervical dilatation ≥3 cm will be sent to the labour ward for amniotomy. If fetal heart tracing is reassuring after amniotomy, randomization will be performed. Randomisation will be carried out by opening the lowest-numbered sealed opaque envelope, randomised in 1:1 ratio with blocks of 4 and 8, into the intervention group (group 1) or the control group (group 2).

Participants in Group 1 will be subjected to an 8-hour vaginal examination interval while participants in Group 2 will be subjected to a 4-hour vaginal examination interval. Participants in both groups will be subjected to additional vaginal examination as per standard care in the events of:

1. Prior to administration of analgesia or epidural
2. Fully dilated cervical os
3. Application of fetal scalp electrode
4. Non-reassuring fetal heart tracing

Labour progress and uterine activity will be plotted on a partogram. Fetal heart rate activity will be monitored continuously during labour.
Following delivery, maternal satisfaction will be rated by the participants in both groups via a Visual Numerical Rating Scale (VNRS) with scoring from 0-10. Data will be collected as per the case report form. Detail of participants delivery outcomes will be retrieved.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Maternal satisfaction of labour care measured using a visual numerical rating score from 0-10, assessed after delivery
2. Duration of active labour, defined as the amniotomy to delivery interval

Secondary outcome measures
Recorded at delivery:
1. Mode of delivery - vaginal delivery or assisted delivery or caesarean section in each group, in numbers and percentage
2. Rate of caesarean section - percentage of caesarean section in each group
3. Highest intrapartum and day 1 postpartum fever, defined as a single temperature reading of ≥38°C, documented as present or not
4. Analgesia used in active labour, documented as requiring analgesia or not
5. Estimated blood loss, quantified by healthcare worker attending to delivery, after delivery
6. Apgar score of baby measured at 1 and 5 minutes after birth
7. Arterial cord pH, from cord blood taken after delivery and before placenta expulsion and recorded in case report form
8. Birth weight - weight of baby in grams immediately after delivery
9. Neonatal care admission requirement within 24 hours of life, documented as requiring admission or not

Overall study start date
01/04/2021

Completion date
11/10/2022

Eligibility

Key inclusion criteria
1. Multiparous women
2. Aged 18 years and above
3. Gestational age of ≥37 weeks at enrolment of scheduled induction of labour
4. Cephalic presentation
5. Singleton pregnancy
6. Women who had cervical ripening with Foleys catheter and favourable cervix with cervical dilatation of 3 cm or greater (suitable for amniotomy) with contraction <1:10
7. Reassuring fetal cardiotocography (CTG) tracing

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
202

Total final enrolment
204

Key exclusion criteria
1. Previous uterine incision/injury (caesarean delivery, myomectomy, perforation)
2. Gross fetal anomaly
3. Contraindication for vaginal birth
4. Estimated fetal weight ≥4.0 kg before induction

Date of first enrolment
11/10/2021

Date of final enrolment
11/10/2022

Locations

Countries of recruitment
Malaysia

Study participating centre
University Malaya Medical Centre
Lembah Pantai
Kuala Lumpur
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59100

Sponsor information

Organisation
University Malaya Medical Centre

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.ummc.edu.my/#

ROR
https://ror.org/00vkrxq08

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Malaya Medical Centre

Results and Publications

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

Intention to publish date
11/10/2023

Individual participant data (IPD) sharing plan
The data sets generated during and analysed during my study will be available upon request from Dr Aishah Mohd (aishah.mohd@ummc.edu.my). Access to data will be granted to investigators and representatives from Sponsor(s) for monitoring and/or audit purposes only
Demographic and clinical data will be derived from medical records. A case report form will be used for data collection and a new ID will be given to the patient, no personal information will be available on patient CRF. The data collection will be performed by the investigators.
Data will be stored in a locked cabinet in the investigator's office where only the investigator will have the access to. It will be kept for a duration of 7 years before it is destroyed.
All participants' anonymity is maintained. The participants will be given a unique Study ID upon recruitment into this study. This Study ID will be the only mean of identifying on the Case Report Form (CRF) and electronic database. There will be a separate document (Participants Identification List) containing the participant's name, identification card number, telephone number and address along with their Study ID. This document will only be accessible to Investigators and will be stored separately from the data documents.
The result of this study may be presented at medical conferences or published in medical journals. However, all data obtained will be reported with no reference to a specific individual. Hence, every participant's data will remain confidential.

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	29/04/2021	06/10/2021	No	Yes
Protocol file	version 4	21/07/2021	24/11/2021	No	No
Results article		04/03/2024	05/11/2024	Yes	No