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Comparing length of labour for early and delayed breaking of the waters following induction of labour in women who have previously had a normal vaginal birth

Submission date
27/09/2020

Recruitment status
No longer recruiting

Registration date
29/09/2020

Overall study status
Completed

Last Edited
17/08/2022

Condition category
Pregnancy and Childbirth

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Induction of labour involves contractions of the uterus (womb) during pregnancy, in order to achieve vaginal birth. A healthcare professional might recommend labour induction for various reasons, primarily when there is concern for the mother's or baby's health if labour does not start or does not progress more quickly. One method of inducing labour is to use a Foley catheter, which inserts an inflatable balloon into the cervix that can be used to start opening up the cervix. It is a gentle method of induction and does normally stimulate contractions on its own. To start contractions, women are given the hormone oxytocin using a drip. Oxytocin is released during labour naturally. The amniotic sac (liquid-filled membrane that surrounds the baby in the womb) can also be ruptured (broken) rather than waiting for it to break naturally, which is known as the waters breaking, to help get labour underway. This study aims to compare whether labour is shorter if the amniotic sac is ruptured at the same time as the oxytocin drip starts compared with if the sac is ruptured 4 hours later in women who have already had a Foley catheter inserted.

Who can participate?
Women who had a vaginal delivery previously at at least 24 weeks of pregnancy, who have been pregnant for at least 37 weeks in the current pregnancy, and are having a planned labour induction using a Foley catheter

What does the study involve?
Participants will be randomly allocated to either early rupture of membrane or delayed rupture of membrane (after 4 hours or earlier if clinically warranted) with ongoing oxytocin infusion. After delivery, participants will be asked to provide their level of satisfaction with the labour process.

What are the possible benefits and risks of participating?
The procedure may shorten the birth process, and improve the satisfaction level of the mother.

Information obtained from this study will help in changing the current labour ward practices. Rupture of the membrane may cause some pain and discomfort, and oxytocin infusion can cause changes in foetal heart rate. However major complications are not anticipated, since these methods are commonly used and the healthcare staff are experienced in using them.

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 2020 to July 2021 (updated 28/06/2021, previously: June 2021; updated 01/03/2021, previously: March 2021)

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

Who is the main contact person
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
NMRR-20-1275-55558

Study information

Scientific Title
Early amniotomy and immediate oxytocin versus oxytocin and delayed amniotomy following cervical ripening with a Foley catheter in multiparous women

Study objectives
Multiparous women receiving titrated oxytocin and early amniotomy following cervical ripening with Foley catheter will experience a shortened interval to delivery versus those who receive delayed amniotomy with concurrent oxytocin following cervical ripening with Foley catheter.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/9/2020, University Malaya Medical Centre Medical Research Ethics Commitee, (Lembah Pantai, 59100 Kuala Lumpur, Malaysia; +60 379493209; ummc@ummc.edu.my), ref: 2020623-8807

Study design
Single centre interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Induction of labour in multiparous women

Interventions
All multipara who had a Foley induction are recruited into this study. Eligible women will be provided with a patient information sheet and written consent will be taken. After the removal of Foley or after spontaneous expulsion of the Foley catheter, vaginal examination will be performed, and those women with cervical dilatation ≥3 cm with a well-applied head presentation will be randomized to either early or delayed amniotomy with concurrent oxytocin. The randomisation will be done by opening a sealed opaque envelope. Women in the early amniotomy group will have amniotomy done with oxytocin drip, and while in the delayed amniotomy group will be started on oxytocin drip and after 4 h amniotomy will be performed, or

earlier if clinically warranted. All the primary and secondary outcomes will be collected after delivery.

The amniotomy is done by using the amniotic hook to make a small nip on the amniotic sac overlying the presenting part (fetal head, vertex) during the vaginal examination and as a result, the liquor (amniotic fluid) is drained.

Intervention Type
Mixed

Primary outcome measure
Intervention to delivery interval measured as the time in min from oxytocin initiation to delivery of the baby taken from the mother's medical records.

Secondary outcome measures
Maternal outcome measures:
1. Caesarean rate measured as the percentage of women delivered via Caesarean delivery at the end of the study using patient records
2. Maternal satisfaction with the birth process using a visual numeric scale at delivery
3. Intrapartum and postpartum fever (temperature of 38°C or greater) reported through the process of labour and within 24 h after delivery using patient records
4. Analgesic used in labour that is reported throughout the process of labour and measured at the time of delivery by using case report forms
5. Delivery blood loss documented upon delivery and measured at the time of delivery using case report forms
6. Uterine hyperactivity defined as six or more contractions in 10 min over two consecutive 10-min periods or a sustained contraction of 2 min or longer or associated with fetal heart abnormality documented throughout the labour process and measured at delivery using case report forms
7. Cardiotocography (CTG) abnormality defined as suspicious or pathological according to NICE guideline 2017 and documented throughout the labour process and measured after delivery using case report forms
8.Mode of delivery with indication documented upon delivery and measured at the time of delivery using case report forms

Neonatal outcome measures:
1. Apgar score at 1 and 5 min documented upon delivery and measured at the time of delivery using case report forms
2. Arterial cord blood pH and base excess documented upon delivery and measured at the time of delivery using case report forms
3. Birth weight measured using weighing scale and documented upon delivery and measured at the time of delivery using case report forms
4. Neonatal care admission measured using patient records:
4.1. Admission to Paediatric ICU after delivery within 24 h of delivery
4.2. Admission to Special Care Nursery after delivery within 24 h of delivery

Overall study start date
01/04/2020

Completion date
30/07/2021

Eligibility

Key inclusion criteria
1. Multiparous women (at least one prior vaginal birth at greater than 24 weeks gestation)
2. Aged 18 years and above
3. Planned labour induction
4. Gestational age of >37 weeks at enrolment of scheduled induction of labour. (Gestational age estimations were all supported by ultrasonographic dating.)
5. Cephalic presentation
6. Singleton pregnancy
7. Women who had a cervical riperning with Foley catheter only, and favourable cervix with cervical dilatation of 3 cm or greater (suitable for amniotomy) with contraction frequency <1 in a 5-min period
8. Intact membranes
9. Reassuring fetal heart rate tracing

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
232

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
5. Low birth weight baby, with birth weight <2.0 kg before induction
6. Ruptured membranes

Date of first enrolment
01/10/2020

Date of final enrolment
30/07/2021

Locations

Countries of recruitment
Malaysia

Study participating centre
University Malaya Medical Centre
Lembah Pantai
Petaling Jaya
Malaysia
59100

Sponsor information

Organisation
University Malaya Medical Centre

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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

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 high-impact peer-reviewed journal. The protocol is not available online but can be provided upon request.

Intention to publish date
31/01/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		23/07/2022	17/08/2022	Yes	No