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Comparison between early versus delayed breaking of the waterbag (amniotic sac) in terms of labour duration in childbirth

Submission date
20/09/2020

Recruitment status
No longer recruiting

Registration date
22/09/2020

Overall study status
Completed

Last Edited
29/01/2021

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Labour induction — also known as inducing labour — is the stimulation of uterine contractions during pregnancy before labour begins on its own to achieve a vaginal birth. A health care provider might recommend labour induction for various reasons, primarily when there's a concern for a mother's health or a baby's health. One of the most important factors in predicting the likelihood of successful labour induction is how soft and distended the opening of the womb (cervix) is.
The frequency of induction of labour has dramatically risen over the last decades. Mechanical induction using an inflatable balloon on a tube placed into the cervix (Foley catheter) is a common induction method. Typically, patients who are induced with a Foley catheter will not have a contraction on their own, therefore the usage of the drug 'oxytocin' combined with artificial rupture of the amniotic sac (waterbag that surrounds the baby) is usually needed to initiate labour. (Oxytocin is a drug that can make contractions stronger and more regular and can start to work quite quickly).
The aim of this study is to investigate the hypothesis that early artificial opening of the amniotic sac (amniotomy) and immediate oxytocin will shorten labour duration.

Who can participate?
Women who have not previously given birth (nulliparous) who are over 37 weeks pregnant and planned for induction with a Foley catheter.

What does the study involve?
Participants will be randomly allocated to receive immediate amniotomy and administration of oxytocin or will receive oxytocin and amniotomy after 4 hours, or earlier if warranted. After the delivery, participants will be asked to provide their level of satisfaction with the delivery.

What are the possible benefits and risks of participating?
Benefits: The procedure may shorten the birth process and improve satisfaction in the birth process. Information obtained from this study will help to improve the management of labour in the future.

Risks: Amniotomy can cause some pain and discomfort. Oxytocin can cause changes in fetal heart monitoring. Major complications are not anticipated.

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 March 2021 (updated 29/01/2021, previously: January 2021)

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

Who is the main contact?
Nur Adlyn Binti Hasan
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Contact information

Type(s)
Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
NMRR-20-1797-55559

Study information

Scientific Title
Immediate oxytocin and early amniotomy versus immediate oxytocin and delayed amniotomy following cervical ripening with foley catheter in nulliparous women

Study objectives
Nulliparous receiving titrated oxytocin infusion after Foley ripening for labour induction, concurrent amniotomy (with the start of oxytocin infusion) compared to delayed amniotomy will shorten the interval to delivery.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 12/09/2020, Medical Research Ethics Committee, University Malaya Medical Centre (Lembah Pantai, 59100 Kuala Lumpur, Malaysia; +60 379493209; ummc@ummc.edu.my), ref: 2020623-8808

Study design
Single- center interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
induction of labour in nulliparous pregnant women

Interventions
All nulliparous women having Foley catheter insertion are recruited in our delivery suite and antenatal ward. Eligible women will be provided with a patient information sheet and written consent will be taken. After the removal of the Foley catheter or spontaneous expulsion of the catheter, the vaginal examination will be performed, and those women with cervical dilatation of ≥3cm will be randomized to either early amniotomy and oxytocin group or oxytocin and delayed amniotomy group. The randomisation will be carried out by sealed envelope.
Women who in the early amniotomy group will have amniotomy done followed by IV oxytocin administration.
Women in the delayed amniotomy group will receive IV oxytocin and planned amniotomy after 4 hours, or earlier if warranted.
All the primary and secondary outcomes are collected after delivery.

Intervention Type
Mixed

Primary outcome(s)
Intervention to delivery interval measured as the time (min) from oxytocin initiation to delivery of the baby

Key secondary outcome(s))
Maternal outcome:
1. Caesarean rate measured as the percentage of women delivered via caeserean delivery at the end of study using patient records
2. Maternal satisfaction with the birth process using visual numerical rating scale at delivery
3. Intrapartum and postpartum fever (temperature of 38C or greater) reported throughout the

process of labour and within 24 hours after delivery
4. Analgesic used in labour that is reported throughout the process of labour and measured at the time of delivery 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 minutes over two consecutive 10-minute periods or sustained contraction 2 min or longer or association with fetal heart rate abnormality which documented throughout the labour process and measured at delivery using case report forms
7. 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:
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 pH & Base excess documented upon delivery and measured at the time of delivery using case report forms
3. Birth weight measured using weigh scale and documented upon delivery using case report forms
4. Neonatal care admission measured using patient records:
4.1. Admission to NICU after delivery within 24 hours of delivery
4.2. Admission to Paediatric ICU after delivery within 24 hours of delivery
4.3. Admission to Special care nursery after delivery within 24 hours of delivery

Completion date
31/03/2021

Eligibility

Key inclusion criteria
1. Female aged 18 years and above
2. Nulliparous
3. Gestational age of ≥37 weeks at enrolment Scheduled induction of labour (Gestational age estimations supported by ultrasonographic dating)
4. Planned labour induction
5. Singleton pregnancy
6. Cephalic presentation
7. Women who had a cervical ripening with Foley catheter only and favourable cervix with cervical dilatation of 3 cm or greater (suitable for amniotomy) with contraction every 1 to 5 min
8. Intact membranes
9. Reassuring cardiotocogram

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Adult

Lower age limit
18 years

Sex
Female

Key exclusion criteria
1. Previous uterine incision/ injury (caesarean delivery, myomectomy, perforation)
2. Gross fetal anomaly
3. Contraindication for vaginal birth
4. Fetal weight clinically estimated to be ≤2 kg or ≥4kg before induction and confirmed by ultrasound
5. Ruptured membranes

Date of first enrolment
25/09/2020

Date of final enrolment
31/03/2021

Locations

Countries of recruitment
Malaysia

Study participating centre
University Malaya Medical Centre
Lembah Pantai
Kuala Lumpur
Malaysia
50603

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 datasets generated and/or analysed during the current study will available upon request from the principal investigator (Nur Adlyn Hasan; adlyn@ummc.edu.my) after the overall trial end date. Datasets are confidential and any data sharing will have to go through the Medical Research Ethics Committees at University Malaya Medical Centre.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes