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Comparison between active management and conservative management of term nulliparas with prolonged latent phase.

Submission date
22/10/2015

Recruitment status
No longer recruiting

Registration date
05/11/2015

Overall study status
Completed

Last Edited
13/05/2020

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol

Background and study aims
Pregnant women that are about to give birth may experience very early labour like contractions and/or pain. This is called the latent phase of labour. They then may progress into true active labour within next few hours or may remain in the latent stage for up to 48 hours or more. Prolonged latent phase according has been defined as labour like pain and/or contractions that lasts more than 20 hours. A dilemma exists on whether labour should be induced or to wait for the spontaneous progression into labour. This is sometimes compounded by the pressure to do something by the woman in labour. What we do know that, in a small number of cases, induction does fail; the baby is then delivered by caesarean delivery. Waiting for spontaneous progression into labour does not necessarily guarantee successful vaginal birth, though the chances may be a bit higher than induction. Studies have shown that early admission in latent phase may lead to medical intervention and caesarean section. Staying at home until active phase start is better but for some the pain may be too unbearable, needing admission. We want to study whether medical induction after a day of admission is better or to wait for spontaneous onset of active labour. The aim of this trial is to study and compare the outcome between early versus expectant management of latent phase of labour for patients who have not delivered before. The results of this study should help clinicians in treating patients in the latent phase of labour.

Who can participate?
Women admitted to hospital in the latent phase of labour and at 39-41 weeks pregnant.

What does the study involve?
Participants are randomly allocated to one of two groups. Those in group 1 (active management group) are induced. Those in group 2 (expectant management group) await spontaneous onset of labour.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
University Malaya Medical Center (Malaysia)

When is the study starting and how long is it expected to run for?
June 2015 to May 2016.

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

Who is the main contact?
1. Dr Lindy Bak Li Mei (public)
2. Professor Noor Azmi Mat Adenan (public)
3. Professor Tan Peng Chiong (public)
4. Dr Syeda Zaidi (public)

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Additional identifiers

Study information

Scientific Title
Induction of labour compared to expectant management of term nulliparas with prolonged latent phase: a randomised controlled trial

Study objectives
There is no significant difference in active and conservative management for term nulliparas with prolonged latent phase.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. University Malaya Medical Center Ethics Committee, 25/02/2015, ref: MECID: 20151-971
2. National Medical Research Registry, 06/01/2015, ref: NMRR-15-16-23886

Primary study design
Interventional

Study design
This is a randomised controlled study

Study type(s)
Other

Health condition(s) or problem(s) studied
Prolonged latent phase or the best management for it.

Interventions
Each woman will be randomly allocated to one of two groups:
1. Early induction group
2. Expectant management group
Spontaneous onset of active phase of labor is awaited as long as possible until delivery. These women will be kept in the hospital for further observation.

All patients will be followed up until they deliver.

Intervention Type
Other

Primary outcome(s)
The primary outcome will be the mode of delivery (caesarean section or vaginal delivery)

Key secondary outcome(s)
1. Duration of labor (from participation to active phase and to second stage of labour)
2. Initial Bishop score and VAS score upon admission
3. Any analgesia needed during the latent phase
4. Any intrapartum exogenous oxytocin stimulation during labor
5. Any hyperstimulation
6. Postpartum hemorrhage
7. Patient's satisfaction score and neonatal outcomes

Patient's score will be given according to the Likert scale based on a few statements regarding their experience during the study.

Neonatal outcomes:
1. 5-min Apgar score below 7
2. Cord artery metabolic acidosis (pH ≤ 7 and BE ≤ 12)
3. Birthweight
4. Any admission to the neonatal intensive care unit (NICU) immediately after delivery

Completion date
31/05/2016

Eligibility

Key inclusion criteria
1. Nulliparous women with singleton fetus in cephalic presentation
2. The gestational age from 39 weeks +0 until 41 completed weeks confirmed by ultrasound performed before 20 weeks period of gestational
3. An overnight admission for latent phase of labor and still having contractions of at least 1:30
4. Cervical dilatation will have to be 3cm and below with intact membranes shortly prior to the participation
5. Reassuring cardiotocogram

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Total final enrolment
318

Key exclusion criteria
1. Those who do not fulfill the inclusion criteria
2. Those who do not agree to participate in the study
3. There should be no complaints of reduced fetal movements or leaking liqour upon presentation.
4. Patients with hypertensive disease in pregnancy, gestational diabetes and significant maternal disease will be excluded from the study
5. Estimated fetal weight more than 4kg or less than 2kg will not be included in the study
6. No other fetal or maternal indication to expedite delivery

Date of first enrolment
01/06/2015

Date of final enrolment
31/05/2016

Locations

Countries of recruitment
Malaysia

Study participating centre
University Malaya Medical Center
Jalan University
Kuala Lumpur
Malaysia
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Sponsor information

Organisation

University Malaya Medical Center

ROR
https://ror.org/00vkrxq08

Funder(s)

Funder type
University/education

Funder Name
University Malaya Medical Center (Malaysia)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	11/12/2019	13/05/2020	Yes	No