

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

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| Submission date 22/10/2015 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 05/11/2015 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 13/05/2020 | Condition category Pregnancy and Childbirth | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| | | <input type="checkbox"/> 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**Protocol serial number**

N/A

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

Study design

This is a randomised controlled study

Primary study design

Interventional

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 ($\text{pH} \leq 7$ and $\text{BE} \leq 12$)
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 liquor 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 |