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Regular (4-Hourly) compared with restricted (avoidance unless indicated) vaginal examination in labour induction with an oral misoprostol regime

Submission date
15/11/2016

Recruitment status
No longer recruiting

Registration date
18/11/2016

Overall study status
Completed

Last Edited
18/12/2019

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
Although most labours begin naturally, however around one third of women need help to get started. In these cases, a healthcare professional will often “induce” labour. Although the aim of induction is to achieve a vaginal delivery, it is not always successful and some women end up having a caesarean section (an operation where the child is delivered through a cut in the abdomen). Misoprostol is a drug used as a cheap and effective way of inducing labour, and studies have found that its use has the lowest possibility of caesarean sections. It is common practice to perform vaginal examinations (VE) or assessments on a regular basis during induction of labour with this type of drug to assess progress so that the waters can be broken as soon as possible. Following breaking of the waters, the oxytocin (hormone) drip can then be started to produce strong contractions to speed up delivery of the baby. If misoprostol is given vaginally then VE’s are unavoidable, however if the drug is given by mouth then they may not be necessary. VE can cause discomfort and distress particularly with first time mothers. The aim of this study is to look at success of labour induction and patient satisfaction when participants receive the normal amount or a restricted amount of VE’s during induction of labour with misoprostol taken by mouth (oral).

Who can participate?
Pregnant women who need to have labour induced with misoprostol.

What does the study involve?
Participants are randomly allocated to one of two groups. Participants in both groups are given misoprostol by mouth every four hours to induce labour, with a maximum of three doses to be given in the first 12 hours. If this does not work, then the process is repeated after 24 hours. Those in the first group have a vaginal examination before every dose. Those in the second group only undergo vaginal examinations if there are signs that there is a problem or that the

patient has moved to the next stage of labour. Participants in both groups are followed up 12 hours after labour is induced and after delivery to find out how successful the induction has been and whether the women are satisfied with their care.

What are the possible benefits and risks of participating?
There are no notable benefits involved with participating. There is a small risk that the restricted vaginal examination group may have a longer period between induction and delivery and there is a risk that those in the regular vaginal examination group are exposed to a higher number of potentially uncomfortable 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?
July 2016 to August 2018

Who is funding the study?
University Malaya (Malaysia)

Who is the main contact?
1. Dr Win Sandar Tin (public)
2. Professor Tan Peng Chiong (scientific)

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2016728-4061

Study information

Scientific Title
Comparing regular with restricted vaginal assessment in nulliparous women undergoing labour induction with oral misoprostol: a randomised trial

Study objectives
The aim of this study is to evaluate whether regular vaginal examinations (VEs) compared to a regimen where VEs are restricted, expedite the induction process and influence patient satisfaction in nulliparas undergoing oral misoprostol induction of labour.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Medical Ethics Committee, University Malaya Medical Center, 20/09/2016, ref: 2016728-4061

Study design
Single-centre randomised 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 at term in nulliparas (various indications)

Interventions
Participants are randomised to one of two groups using a random number generator in blocks of 4 or 8 in a 1:1 ratio.

Regular Vaginal Assessment group: A vaginal examination will be performed with a view to performing amniotomy and commence titrated oxytocin infusion if the cervix is found to be suitable preceding each scheduled 4-hourly dose of oral misoprostol.

Restricted Vaginal Assessment group: Each 4-hourly 3-dose schedule of oral misoprostol may be administered without a prior vaginal assessment unless specific indications are present. Indications for vaginal assessment are:
1. Membrane rupture
2. Excessive vaginal bleeding
3. Suspected uterine overstimulation
4. Fetal concerns
5. Maternal concerns
6. Suspicion of established labour (e.g. need for strong analgesia like an epidural)
7. Suspicion of second stage of labour

In both groups, oral misoprostol is administered every 4 hours (at commencement, then 4 and 8 hours later) to induce labour. A maximum of 3 doses may be administered in the first 12 hours. Patients who are not sufficiently responsive and still requiring cervical ripening may have the process repeated after 24 hours.

Routine standard of care applies to both trial arms in all other aspects. Care providers may manage (including additional vaginal assessments or omitting oral misoprostol) during the 8-hour study period at their sole discretion based on perceived clinical need of the participants.

Participants in both groups are followed up 12 hours after commencement of labour induction and then again after delivery.

Intervention Type
Other

Primary outcome measure
1. Patient satisfaction with the birth process is evaluated using a 11-point visual numerical rating score (VNRS) self-marked by participants before discharge from hospitalisation for delivery
2. Induction to vaginal delivery interval is measured using recorded start of induction to recorded time of vaginal birth in her medical records
3. Vaginal delivery rate in 24 hours is derived from dichotomization of induction to vaginal delivery data

Secondary outcome measures
1. Patient satisfaction with the induction process is measured using a 11-point visual numerical rating score (VNRS) self-marked by participants at 12 hours after the start of labour induction

2. Patient preference on the vaginal assessment regime in a future labour induction is measured using Likert scale responses to a statement at 12 hours and before discharge from hospitalisation for delivery
3. Total numbers of vaginal examination in first 12 hours of labour induction is measured by abstracting from medical records after delivery
4. Total oral misoprostol doses used during birth process is measured by abstracting from medical records after delivery
5. Other modes (other prostaglandins, route, balloon) used for labour induction is measured by abstracting from medical records after delivery
6. Oxytocin use in labour is measured by abstracting from medical records after delivery
7. Epidural in labour is measured by abstracting from medical records after delivery
8. Mode of delivery is measured by abstracting from medical records after delivery
9. Delivery blood loss is measured by abstracting from medical records after delivery
10. Neonatal condition… is measured using the Apgar score at 5 minutes by abstracting from neonatal medical records after delivery
11. Admission of newborn to neonatal ward is measured by abstracting from neonatal medical records after delivery
12. Cord blood pH and base excess is measured by abstracting from neonatal medical records after delivery
13. Induction to hospital discharge interval (maternal) is measured by using recorded date of start of labour induction and date of hospital abstracting from medical records

Overall study start date
28/07/2016

Completion date
31/08/2018

Eligibility

Key inclusion criteria
1. Scheduled induction of labour (various indications) with oral misoprostol
2. Nulliparous women (no previous vaginal delivery beyond 20 weeks of gestation)
3. Term gestation (on or after 37 weeks)
4. Singleton gestation
5. Reassuring pre-induction cardiotocograph
6. Cephalic indication
7. Participant aged 18 years old and above
8. No contraindication to vaginal delivery

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
200 participants (single centre)

Total final enrolment
204

Key exclusion criteria
1. Patients with regular contractions (≥ 2 in 10 minutes)
2. Ruptured membranes
3. Previous uterine surgery
4. Known prostaglandins allergy

Date of first enrolment
26/11/2016

Date of final enrolment
21/09/2017

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

Sponsor details
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Sponsor type
Other

ROR
https://ror.org/00vkrxq08

Funder(s)

Funder type
University/education

Funder Name
University Malaya

Results and Publications

Publication and dissemination plan
Intention to publish in a peer reviewed journal.

Intention to publish date
31/08/2019

Individual participant data (IPD) sharing plan
The trial data will be held at University Malaya and may be made available subject to specific approval by its ethics committee.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/04/2019	18/12/2019	Yes	No