

Comparing 3-hourly with 6-hourly dinoprostone vaginal tablet for labour induction in nulliparous women with an unfavourable cervix at term

Submission date 28/03/2013	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 23/04/2013	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 23/04/2013	Condition category Pregnancy and Childbirth	☐ Individual participant data
		☐ Record updated in last year

Plain English summary of protocol

Background and study aims

Labour induction is frequently inefficient and ineffective in women who are expecting their first child and have unfavourable cervixes. Only 36% deliver vaginally within the first 24 hours and 40% eventually go on to have a Caesarean delivery. The standard treatment for labour induction for these women is a 3 mg dinoprostone tablet given vaginally, followed six hour later by a second dose if the cervix is still unripe.

The aim of the study is to see whether administering a second 3 mg dinoprostone dose at three hours, followed if needed by a third dose at six hours, induces labour better compared to the standard treatment.

Who can participate?

Women scheduled to have an induction of labour and are at term (37 weeks or more), expecting their first baby who is in cephalic presentation, with intact membranes, the cardiotocogram is reassuring and cervix is unripe.

What does the study involve?

Women will be randomly allocated to one of two groups: either 3-dose or 2-dose plus placebo dinoprostone for labour induction. All women will receive a first dose of 3 mg dinoprostone vaginally as standard. Three hours later, a vaginal examination and cardiotocography will be performed and a second dose of either 3 mg dinoprostone or identical looking placebo tablet (neither participant nor her doctor will know which is given) will be administered vaginally if the cervix is still unripe. This is followed in another three hours by another assessment and if the cervix is still unripe, a dose of 3 mg dinoprostone will be given. Following this, further management of the labour induction is up to the providers discretion.

What are the possible benefits and risks of participating?

The three-dose treatment may be more efficient compared to the standard treatment. But the three dose treatment may have more adverse events like excessive contractions which may need further treatment including the need for Caesarean delivery.

Where is the study run from?

The study is conducted in the Delivery Suite of the University of Malaya Medical Centre, a tertiary referral hospital with full-fledged operating theatres and neonatal intensive care unit (Malaysia).

When is the study starting and how long is it expected to run for?

The trial started in February 2013 and is expected to be completed within 18 months.

Who is funding the study?

University of Malaya (Malaysia)

Who is the main contact?

Dr Aizura Adlan

Contact information

Type(s)

Scientific

Contact name

Dr Aizura Adlan

Contact details

Department of Obstetrics & Gynaecology

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50603

Additional identifiers

Protocol serial number

642.13

Study information

Scientific Title

Comparing 3-hourly with 6-hourly dinoprostone vaginal tablet for labour induction in nulliparous women with an unfavourable cervix at term: A randomized controlled trial

Study objectives

We hypothesize that a more intensive regimen for labour induction using 3-hourly (to a maximum 3 doses) compared to 6-hourly (to a maximum 2 doses) dinoprostone (3 mg) vaginal tablets can result in more vaginal deliveries within 24 hours and improve maternal satisfaction with the birth process without increasing the risk of uterine hyperstimulation.

Ethics approval required

Old ethics approval format

Ethics approval(s)

University of Malaya Medical Centre Medical Ethics Committee, 19th March 2008, ref: 642.13

Primary study design

Interventional

Study design

Double blind randomized controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Labour induction in nulliparous women with an unfavourable cervix at term

Interventions

Regimen 1

- a) Dinoprostone (3 mg) vaginal tablet, followed 3 hours later by
- b) Dinoprostone (3 mg) vaginal tablet if still indicated, followed 3 hours later by
- c) Dinoprostone (3 mg) vaginal tablet if still indicated

or

Regimen 2

- a) Dinoprostone (3 mg) vaginal tablet, followed 3 hours later by
- b) Identical placebo vaginal tablet if still indicated, followed 3 hours later by
- c) Dinoprostone (3 mg) vaginal tablet if still indicated

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

dinoprostone

Primary outcome(s)

1. Vaginal delivery in 24 hours
2. Maternal satisfaction with the birth process using a 10 point numerical rating scale

Key secondary outcome(s)

1. Mode of delivery (and indications for operative delivery)
2. Neonatal outcome (admission, umbilical cord blood pH, Apgar score)

3. Analgesia use in during induction and labour
4. Cardiotocogram abnormalities in first 12 hours of labour induction (including tachysystole, hypertonus, hyperstimulation)
5. Meconium stained liquor
6. Blood loss during labour and delivery
7. Maternal fever (any maternal temperature ≥ 38.0 C during labour or before discharge)
8. Maternal pain score at 6 hours of labour induction (if undelivered)
9. Induction to delivery interval
10. Induction to hospital discharge interval

Completion date

31/01/2014

Eligibility

Key inclusion criteria

1. Scheduled for induction of labour
2. Nulliparous (no previous delivery > 20 weeks)
3. Term gestation (≥ 37 weeks)
4. Bishop score on recruitment ≤ 6
5. Intact membranes
6. Singleton pregnancy
7. Cephalic presentation
8. Reassuring cardiotocogram

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

1. Previous uterine incision or injury (e.g. myomectomy, perforation)
2. Known severe fetal anomaly
3. No significant contractions (< 1 in 10 minutes)
4. Allergy to dinoprostone

Date of first enrolment

01/02/2013

Date of final enrolment

31/01/2014

Locations

Countries of recruitment

Malaysia

Study participating centre

Department of Obstetrics & Gynaecology

Kuala Lumpur

Malaysia

50603

Sponsor information**Organisation**

University of Malaya (Malaysia)

ROR

<https://ror.org/00rzspn62>

Funder(s)**Funder type**

University/education

Funder Name

University of Malaya (Malaysia) (H-20001-00-E000066)

Alternative Name(s)

University of Malaya, University Malaya, Malayan University, King Edward VII College of Medicine, Raffles College, University of Malaya in Singapore, , , , UM

Funding Body Type

Government organisation

Funding Body Subtype

Universities (academic only)

Location

Malaysia

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary