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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

Registration date
23/04/2013

Overall study status
Completed

Last Edited
23/04/2013

Condition category
Pregnancy and Childbirth

[ ] 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 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 grous: 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
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design
Double blind randomized 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 the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Labour induction in nullliparous 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 (3mg) 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 (3mg) vaginal tablet if still indicated

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
dinoprostone

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

Secondary outcome measures
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 ≥ 380 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

Overall study start date
01/02/2013

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

Age group
Adult

Sex
Female

Target number of participants
A minimum of 238 women

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)

Sponsor details
Lembah Pantai
Kuala Lumpur
Malaysia
50603

Sponsor type
University/education

Website
http://www.um.edu.my/

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, UM

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
Malaysia

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration