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Concurrent vaginal dinoprostone and oxytocin infusion versus oxytocin infusion for labour induction in term nulliparous with prelabour rupture of membranes: a randomised placebo controlled trial

Submission date
06/11/2007

Recruitment status
No longer recruiting

Registration date
16/11/2007

Overall study status
Completed

Last Edited
31/12/2020

Condition category
Pregnancy and Childbirth

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
607.9

Study information

Scientific Title
Concurrent vaginal dinoprostone and oxytocin infusion versus oxytocin infusion for labour induction in term nulliparous with prelabour rupture of membranes: a randomised placebo controlled trial

Acronym
PROXY trial

Study objectives
Concurrent vaginal dinoprostone and oxytocin infusion compared to placebo and oxytocin infusion shortens the labour induction to delivery interval and improves the women's satisfaction with the birth process.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the University of Malaya Medical Ethics Committee on the 28th August 2007.

Study design
Double blind randomised placebo controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Prelabour rupture of membranes

Interventions
Vaginal dinoprostone and oxytocin infusion versus vaginal placebo and oxytocin infusion to induce labour.

Women randomised to concurrent oxytocin infusion and prostaglandin will receive a single dose of prostaglandin (3 mg of dinoprostone as a vaginal tablet) vaginally at commencement of the labour induction process at the same time as the standard infusion regime of oxytocin (infusion regime starting at 2 mU/min and doubling every 30 minutes to a maximum of 32 mU/min or until 4 contractions in 10 minutes if achieved sooner). Women randomised to the opposing arm will receive placebo tablet vaginally and standard oxytocin infusion regime for labour induction.

Continuous Cardiotocographic (CTG) monitoring will in place throughout the induction and labour. Standard management of labour induction and labour apply throughout the trial.

In the event of CTG abnormalities associated with excessive uterine activity, oxytocin infusion can be reduced or stopped, tocolysis effected with terbutaline subcutaneously or expedited operative delivery performed depending on individual circumstances and severity of CTG abnormalities.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Dinoprostone, oxytocin

Primary outcome measure
Primary outcomes will be measured at or soon after delivery:
1. Proportion delivered vaginal delivery within 12 hours of commencement of induction of labour
2. Maternal satisfaction with the birth process using a 10 point visual analog scale

Secondary outcome measures
Secondary outcomes are intrapartum events, peri-delivery events and the "last" secondary outcome (occurence of maternal fever) will be available by hospital discharge of the mother:
1. Induction to delivery interval
2. Mode of delivery
3. Neonatal outcome (admission, umbilical cord blood pH, Apgar score)
4. Analgesia use in labour
5. Cardiotocographic abnormalities in labour (tachysystole, hyperstimulation)
6. Meconium stained liquor
7. Blood loss during labour and delivery
8. Maternal fever (any maternal temperature greater than or equal to 38°C during labour or postpartum before discharge)

Overall study start date
10/11/2007

Completion date
30/09/2008

Eligibility

Key inclusion criteria
1. Ruptured membranes confirmed clinically by demonstration of pooling of liquor at upper vagina on speculum assessment
2. Nulliparous (no previous delivery greater than 20 weeks)
3. Term gestation (greater than 36 weeks)
4. Bishop score on recruitment less than or equal to 6
5. Less than 1 contraction in 15 minutes
6. Singleton foetus
7. Cephalic presentation
8. Reassuring cardiotocogram

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
At least 106 women

Total final enrolment
114

Key exclusion criteria
1. Previous uterine incision
2. Meconium stained liquor at trial entry
3. Gross foetal anomaly
4. Asthma
5. Allergy to prostaglandin

Date of first enrolment
10/11/2007

Date of final enrolment
30/09/2008

Locations

Countries of recruitment
Malaysia

Study participating centre
Department of Obstetrics & Gynaecology
Kuala Lumpur
Malaysia
50603

Sponsor information

Organisation
University of Malaya Medical Centre (Malaysia)

Sponsor details
University of Malaya
Jalan Universiti
Kuala Lumpur
Malaysia
59100

Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/00vkrxq08

Funder(s)

Funder type
University/education

Funder Name
University of Malaya (Malaysia) - internal funding

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2009	31/12/2020	Yes	No