

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

☐ Prospectively registered

☐ Protocol

Registration date

16/11/2007

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

31/12/2020

Condition category

Pregnancy and Childbirth

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

Secondary outcomes are intrapartum events, peri-delivery events and the "last" secondary outcome (occurrence 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)

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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)

ROR

<https://ror.org/00vkrxq08>

Funder(s)

Funder type

University/education

Funder Name

University of Malaya (Malaysia) - internal funding

Results and Publications

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