ISRCTN70322889 https://doi.org/10.1186/ISRCTN70322889

Labour induction in women at term with unfavourable cervix

Submission date	Recruitment status	[ ] Prospectively registered
16/08/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
18/09/2009	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/09/2009	Pregnancy and Childbirth	[ ] Record updated in last year

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
N/A

Study information

Scientific Title
Sustained-release dinoprostone vaginal pessary with concurrent high-dose oxytocin infusion compared sustained-release dinoprostone vaginal pessary followed six hours later by high dose oxytocin infusion for labour induction in women at term with unfavourable cervix: a randomised controlled trial

Study objectives
Can we use concurrent oxytocin infusion with dinoprostone vaginal pessary for cervical ripening and labour induction?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Istanbul Bakirkoy Women and Children Hospitals Local Ethics Board approved on the 7th November 2008 (ref: 162)

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

Health condition(s) or problem(s) studied
Labour induction

Interventions
Women who were assigned randomly to receive the sustained-released dinoprostone (Propess®, Vitalis, Turkey) with concurrent high-dose oxytocin (Group A) had a single dose placed high into the vaginal fornix. This sustained-released product releases dinoprostone at a low but steady rate (0.3 mg/h). It remained in the vagina for up to 12 hours, as recommended by the manufacturer. At the same time, oxytocin infusion at 4 milliunits/min was started for all participants. Oxytocin infusion was doubled every 30 minutes to a maximum of 40 milliunits/min or until four contractions in 10 minutes was achieved.

Women who were assigned randomly to receive the sustained-released dinoprostone followed six hours later by high-dose oxytocin (Group B) had a single dose placed high into the vaginal fornix. A standart high-dose of intravenous oxytocin was administered 6 hours after the

insertion of the vaginal pessary. An initial dose of 4 mU/min was increased at 30 minute intervals by 4 mU/min to a maximum dose 40 mU/min or until four contractions in 10 minutes was achieved.

Intervention Type
Drug

Phase
Phase I

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

Primary outcome measure
Number (rate) of women who went to vaginally deliver within 24 hours of the initiation of the protocol.

Secondary outcome measures
1. Incidence of excess uterine activity (uterine hyperstimulation or uterine tachysystole)
2. Labour induction-to-delivery interval
3. Labour induction-to-active phase interval (defined as at least 6 uterine contractions per 20-minute intervals, with at least 70% effaced cervix and a cervical dilatation of greater than or equal to 4)
4. Total number of doses of dinoprostone pessary used
5. Meconium-stained liquor
6. Mode of delivery
7. Instrumental delivery rate
8. Maternal satisfaction score for the birth process obtained within 24 hours of delivery (a visual analog scale (VAS) with a range of 0 to 10, with higher score denoting greater satisfaction, was used to gauge maternal satisfaction)
9. Visual analogue scale pain score (ranged from 0 to 10, with 0 representing no pain to 10 representing unbearable pain)
10. Rates of maternal and neonatal complications:
10.1. Maternal complications included:
10.1.1. Incidence of maternal side effects (nausea, vomiting, diarrhoea, pyrexia)
10.1.2. Postpartum haemorrhage (blood loss greater than 500)
10.1.3. Third- or fourth-degree lacerations
10.1.4. Intrapartum chorioamnionitis (defined as temperature greater than or equal to 38°C accompanied by maternal or fetal tachycardia [greater than 160 beats/min], uterine tenderness, malodorous amniotic fluid discharge, and/or maternal leukocytosis [white blood cell count greater than 15,000 cell/min^3])
10.1.5. Postpartum endometritis (defined as temperature greater than or equal to 38°C accompanied by uterine tenderness and/or purulent or foul-smelling lochiae beyond the first 24 hours after delivery)
10.2. Neonatal complications noted were:
10.2.1. Apgar scores of less than 7 at 5 minutes
10.2.2. Neonatal jaundice
10.2.3. Rate of admission to the neonatal intensive care unit

Seondary analysis based on parity was also planned.

Overall study start date
01/10/2007

Completion date
01/02/2009

Eligibility

Key inclusion criteria
1. Single live fetus in cephalic presentation
2. Gestational age greater than or equal to 37 weeks as determined by the last menstrual period or by a first- or second-trimester ultrasound scan
3. Bishop score less than or equal to 4
4. Females aged 20 - 40 years

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
500

Key exclusion criteria
1. Any contraindication to vaginal delivery
2. Previous caesarean section
3. Multiple pregnancy
4. Estimated fetal weight greater than 4500 g
5. Breech presentation
6. Antepartum haemorrhage
7. Evidence of fetal distress

Date of first enrolment
01/10/2007

Date of final enrolment
01/02/2009

Locations

Countries of recruitment
Türkiye

Study participating centre

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Sponsor information

Organisation
Istanbul Bakirkoy Women and Children Hospital (Turkey)

Sponsor details
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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Istanbul Bakirkoy Women and Children Hospital (Turkey) - Department of Obstetrics and Gynecology

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