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Prostaglandin E2 vaginal gel or tablets for induction of labour at term

Submission date 25/07/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/09/2010	**Overall study status** Completed	
Last Edited 27/09/2011	**Condition category** Pregnancy and Childbirth	

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

CTA/MHRA No: 13690/0212/001-0001

Study information

Scientific Title
A comparison of the effectiveness of prostaglandin gel and tablet preparations in the induction of labour at term: a randomised controlled trial

Study objectives
One dinoprostone formula is associated with less induction to delivery interval than the other one.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Riverside Ethics Committee approved in 2004 (ref: 04/Q0401/139)

Study design
Randomised double blinded clinical 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
Induction of labour

Interventions
In patients randomised to receive dinoprostone gel, in nulliparous with an unfavourable cervix (modified bishop score less than 4), an initial dose of 2 mg was administered. In multiparaous and nulliparous women with an favourable cervix (modified bishop score 5 to 7), an initial dose of 1 mg was administered. In the patients randomised to receive dinoprostone tablets, 3 mg was administered into the posterior vaginal fornix.

The duration of dinopristone treatment is variable for each patient. It starts at patients admission to the hospital for induction of labour and can last between 1 - 4 days.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Prostaglandin E2

Primary outcome measure
Time interval between induction of labour to delivery in minutes, irrespective of the mode of delivery, and the rate of failed induction of labour leading to caesarean section. Assessed in every patient during the process of labour induction at gestation (greater than or equal to 36+6 to 42 weeks gestation).

Secondary outcome measures
1. Requirement for oxytocin augmentation
2. Incidence of uterine hyperstimulation, defined as uterine tachysystole (with five or more contractions in a 10 minute period for two consecutive 10 minute periods) or uterine hypertonus (a uterine contraction lasting for more than two minutes) resulting in pathological cardiotocography trace that necessitated intervention by administering of a tocolytic or delivery
3. Incidence of intrapartum foetal blood sampling
4. Epidural requirement
5. Mode of delivery
6. Blood loss at delivery
7. Incidence of maternal pyrexia
8. Perineal lacerations require suturing
9. 1 and 5-minute Apgar score
10. Need for admission to NICU

Overall study start date
01/04/2005

Completion date
31/12/2006

Eligibility

Key inclusion criteria
Women undergoing induction of labour with a cephalic presentation (singleton) or first twin cephalic at term (greater than or equal to 36+6 to 42 weeks gestation)

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
220

Key exclusion criteria
1. Favourable cervix (defined as a modified Bishop score of greater than or equal to 8)
2. Any contraindication to vaginal birth
3. Previous uterine surgery (including caesarean section)
4. Unwillingness to participate in the trial

Date of first enrolment
01/04/2005

Date of final enrolment
31/12/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Professor of Obstetrics and Gynaecology
London
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Sponsor information

Organisation
Queen Charlotte's and Chelsea Hospital (QCCH) (UK)

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Sponsor type
Hospital/treatment centre

Website
http://www.imperial.nhs.uk/qcch

ROR
https://ror.org/03af1tj71

Funder(s)

Funder type
Government

Funder Name
Hammersmith Hospitals NHS Trust (UK)

Funder Name
National Institute for Health Research (NIHR) (UK) - Biomedical Research Centre

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	01/05/2011		Yes	No