

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

Submission date 25/07/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 23/09/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 27/09/2011	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Philip Bennett

Contact details
Professor of Obstetrics and Gynaecology
Imperial College Faculty of Medicine
Institute for Reproductive and Developmental Biology
Hammersmith Hospital Campus
Du Cane Road
London
United Kingdom
W12 0NN
+44 (0)20 7594 2141
pbennett@imperial.ac.uk

Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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).

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

United Kingdom

England

Study participating centre
Professor of Obstetrics and Gynaecology
London
United Kingdom
W12 0NN

Sponsor information

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

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

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