

A comparison of the effectiveness of prostaglandin gel and tablet preparations in induction of labour at term.

Submission date 30/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 30/09/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 12/04/2011	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

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N0016158062

Study information

Scientific Title

Study objectives

Is Prostin (dinoprostone) gel more effective in induction of labour than Prostin tablets?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Pregnancy and Childbirth: Labour induction

Interventions

Prostil gel vs Prostil tablet

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

prostaglandin

Primary outcome measure

1. Mode of delivery and indication
2. Time in labour
3. Number of doses of prostaglandin needed
4. Cervical dilation at transfer to labour Ward.
5. Frequency of artificial rupture of membranes
6. Frequency of oxytocin use
7. Frequency of meconium staining of liquor
8. Frequency of uterine tachysystole/hyperstimulation
9. Frequency of need for foetal blood sampling in labour
10. Frequency of need for neonatal resuscitation or transfer to Neonatal Unit

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/11/2004

Completion date

01/11/2006

Eligibility

Key inclusion criteria

Outpatients

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

165

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/11/2004

Date of final enrolment

01/11/2006

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Women's & Children's Services
London
United Kingdom
W12 0HS

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
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Sponsor type
Government

Website
<http://www.dh.gov.uk/Home/fs/en>

Funder(s)

Funder type
Government

Funder Name
Hammersmith Hospital NHS Trust (UK)

Funder Name
Hammersmith Hospital Pharmacy

Funder Name

NHS R&D Support Funding 2004/05

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