

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	☐ Prospectively registered
Registration date 30/09/2005	Overall study status Completed	☐ Protocol
Last Edited 12/04/2011	Condition category Pregnancy and Childbirth	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Not Specified

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(s)

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

Key secondary outcome(s)

Not provided at time of registration

Completion date

01/11/2006

Eligibility

Key inclusion criteria

Outpatients

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

United Kingdom

England

Study participating centre

Women's & Children's Services

London

United Kingdom

W12 0HS

Sponsor information

Organisation

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

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