ISRCTN70152691 https://doi.org/10.1186/ISRCTN70152691

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

Submission date	Recruitment status	[_] Prospectively registered
30/09/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/09/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
12/04/2011	Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr Douglas Keith Edmonds

Contact details
Women's & Children's Services
Queen Charlottes & Chelsea Hospital
Hammersmith Hospital
Du Cane Road
London
United Kingdom
W12 0HS
+44 (0)20 8383 5239
dkedmonds@hhnt.org

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
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

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