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Comparison of oral misoprostol with vaginal prostin for induction of labour at term with prolonged rupture of membranes

Submission date	Recruitment status	[_] Prospectively registered
30/09/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/09/2004	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
10/11/2010	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

N0024125766

Study information

Scientific Title

Study objectives
1. Is oral misoprostol as safe and effective as vaginal prostin?
2. Is patient satisfaction improved with oral misoprostol?
3. Is there a reduction in caesarean section rate with oral misoprostol?

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)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Pregnancy and Childbirth: Labour induction

Interventions
Randomised controlled trial
1. Misoprostol
2. Prostin

Intervention Type
Other

Phase
Not Specified

Primary outcome measure

1. Time of induction to delivery time
2. Pyrexia in labour
3. Mode of delivery
4. Condition of baby at birth

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/04/2003

Completion date
31/03/2004

Eligibility

Key inclusion criteria
200 women with term rupture of membranes fitting our inclusion criteria randomised to receive prostin or misoprostol

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
200

Key exclusion criteria
Does not match inclusion criteria

Date of first enrolment
01/04/2003

Date of final enrolment
31/03/2004

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Obstetrics & Gynaecology
London
United Kingdom
E9 6SR

Sponsor information

Organisation
Department of Health

Sponsor details
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type
Government

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

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Homerton University Hospital NHS Trust (UK)

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	01/04/2008		Yes	No