

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

Submission date 30/09/2004	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 30/09/2004	Overall study status Completed	☐ Protocol
Last Edited 10/11/2010	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
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

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

Not provided at time of registration

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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**

United Kingdom

England

Study participating centre

Department of Obstetrics & Gynaecology

London

United Kingdom

E9 6SR

Sponsor information**Organisation**

Department of Health

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Homerton University Hospital NHS Trust (UK)

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	01/04/2008		Yes	No