

To compare the safety and efficacy of 'low dose' vaginal misoprostol and dinoprostone vaginal gel for induction of labour at term

Submission date 12/09/2003	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 12/09/2003	Overall study status Completed	☐ Protocol
Last Edited 11/09/2013	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

Contact name

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Contact details

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Additional identifiers

Protocol serial number

N0533091848

Study information

Scientific Title

A single-blind randomised controlled trial comparing low dose vaginal misoprostol and dinoprostone vaginal gel for inducing labour at term

Study objectives

To determine if vaginal misoprostol is a better method of inducing labour at term than dinoprostone vaginal gel.

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: Induction of labour

Interventions

1. Misoprostol
2. Dinoprostone

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

1. Uterine tachysystole
2. Hyperstimulation
3. Presence of meconium in the amniotic fluid
4. Apgar Scores at 5 min. Umbilical arterial pH and base deficit
5. Neonatal Unit admission
6. Induction - delivery interval
7. Method of delivery
8. Bishop score at onset of labour
9. Oxytocin requirements in labour
10. Mode of delivery
11. Analgesia requirements in labour

Key secondary outcome(s)

Not provided at time of registration

Completion date

31/01/2004

Eligibility

Key inclusion criteria

1. Women at term (37-42 completed weeks of pregnancy)
2. Single fetus, cephalic presentation
3. Membranes may be intact or ruptured
4. Reactive fetal heart tracing

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

01/07/2000

Date of final enrolment

31/01/2004

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Maternity Unit

Sidcup, Kent

United Kingdom

DA14 6LT

Sponsor information

Organisation

Department of Health (UK)

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Queen Mary's Sidcup 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	01/04/2005		Yes	No