ISRCTN85744560 https://doi.org/10.1186/ISRCTN85744560

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

Registration date
12/09/2003

Overall study status
Completed

Last Edited
11/09/2013

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] 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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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

Study design
Randomised controlled trial

Primary study design
Interventional

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes