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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Number of patients projected for 2000/2001 - 200

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 measure
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

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/07/2000

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

Age group
Adult

Sex
Female

Target number of participants
200

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
England

United Kingdom

Study participating centre
Maternity Unit
Sidcup, Kent
United Kingdom
DA14 6LT

Sponsor information

Organisation
Department of Health (UK)

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

Sponsor type
Government

Website
http://www.doh.gov.uk

Funder(s)

Funder type
Hospital/treatment centre

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