ISRCTN57007037 https://doi.org/10.1186/ISRCTN57007037

# A randomised trial to evaluate misoprostol for induction of labour following prelabour rupture of the amniotic membranes

**Submission date**
21/07/2005

**Recruitment status**
No longer recruiting

**Registration date**
09/09/2005

**Overall study status**
Completed

**Last Edited**
06/10/2009

**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

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
LWH315

# Study information

## Scientific Title

## Acronym
The PROMMIS Trial - Prelabour Rupture Of the Membranes and MISoprostol

## Study objectives
Vaginal misoprostol for cervical priming followed by titrated oral misoprostol is as safe and effective as dinoprostone and/or oxytocin for induction of labour in the presence of prelabour rupture of membranes (PROM)

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
Not provided at time of registration

## Study design
Randomised active controlled parallel group trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet

## Health condition(s) or problem(s) studied
Induction of labour

## Interventions
Randomisation to dinoprostone or misoprostol

## Intervention Type
Drug

## Phase
Not Specified

## Drug/device/biological/vaccine name(s)
Misoprostol, dinoprostone, oxytocin

### Primary outcome measure
1. Caesarean section (measure of safety)
2. Vaginal delivery within 24 hours of trial entry (measure of clinical effectiveness)

### Secondary outcome measures
1. Labour
2. Delivery
3. Pueperium
4. Neonatal Morbidity
5. Satisfaction - Women's satisfaction, Caregiver's satisfaction
6. Womens' and midwives' views and experiences of participating in the PROMMIS Trial

### Overall study start date
01/02/2002

### Completion date
31/12/2005

## Eligibility

### Key inclusion criteria
1. Decision to induce labour in the presence of PROM
2. >34 weeks gestation
3. Singleton, live fetus
4. Normal admission cardiotocograph (CTG)

### Participant type(s)
Patient

### Age group
Adult

### Sex
Female

### Target number of participants
1890 (758 final recruitment)

### Key exclusion criteria
1. Multiple pregnancy
2. Breech presentation
3. Previous Caesarean section

### Date of first enrolment
01/02/2002

### Date of final enrolment
31/12/2005

# Locations

**Countries of recruitment**
England

United Kingdom

**Study participating centre**
**Liverpool Women's Hospital NHS Foundation Trust**
Liverpool
United Kingdom
L8 7SS

# Sponsor information

**Organisation**
Liverpool Women's Hospital NHS Foundation Trust (UK)

**Sponsor details**
University Departments
Liverpool Women's Hospital
Crown Street
Liverpool
England
United Kingdom
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**Sponsor type**
Hospital/treatment centre

**ROR**
https://ror.org/04q5r0746

# Funder(s)

**Funder type**
Government

**Funder Name**
Liverpool Women's Hospital NHS Foundation Trust (UK)

**Funder Name**
NHS Support Funds

# 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 | 01/11/2008 | | Yes | No |