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

Submission date	Recruitment status No longer recruiting	Prospectively registered		
21/07/2005		☐ Protocol		
Registration date 09/09/2005	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	[] Individual participant data		
06/10/2009	Pregnancy and Childbirth			

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 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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

- 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

Completion date

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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

United Kingdom

England

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)

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

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