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

Contact name
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Crown Street
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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
L8 7SS

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