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Immediate delivery versus expectant care in women with ruptured membranes close to term

Submission date	Recruitment status	[_] Prospectively registered
17/03/2005	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
19/04/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/12/2017	Pregnancy and Childbirth	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
358378

Study information

Scientific Title
A randomised controlled trial of immediate delivery versus expectant care in women with ruptured membranes close to term

Acronym
PPROMT - Preterm Prelabour Rupture Of the Membranes close to Term

Study objectives
That early planned delivery of women with PPROM close to term is associated with:
1. Less neonatal and maternal morbidity compared with expectant management
2. Fewer economic costs compared with expectant management

Ethics approval required
Old ethics approval format

Ethics approval(s)
Australia: Northern Sydney Central Coast Area Health Service, 01/06/2004
United Kingdom: Tayside Committee Medical Research Ethics A, 19/01/2006, ref: 05/S1401/187

All other centres will seek ethics approval before recruitment of the first participant.

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Preterm prelabour rupture of membranes

Interventions
Immediate delivery (within 24 hours) versus expectant management.

Added as of 13/02/2009: The duration of follow-up is 4 months post estimated date of confinement (EDC) or the baby's due delivery date at term. The follow-up will be coordinated from the Australian coordinating centre at the Royal North Shore Hospital.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Neonatal sepsis

Key secondary outcome(s)
1. Secondary infant outcomes:
1.1. Respiratory distress
1.2. Perinatal mortality
1.3. Duration of stay in special care unit

1.4. Duration of stay in hospital
1.5. Birth weight
1.6. Apgar score at 5 minutes
1.7. Any assisted ventilation
1.8. Early infant development
2. Secondary maternal outcomes:
2.1. Chorioamnionitis
2.2. Endometritis treated with antibiotics
2.3. Post-partum fever
2.4. Placental abruption
2.5. Induction of labour
2.6. Failed induction of labour
2.7. Caesarean section
2.8. Assisted vaginal delivery
2.9. Maternal satisfaction
2.10. Views of care
2.11. Duration of hospitalisation
2.12. Antenatally and postnatally, time to fully establish breast feeding
2.13. Maternal emotional wellbeing
2.14. Anxiety and depression

Completion date
31/12/2013

Eligibility

Key inclusion criteria
Current inclusion criteria as of 12/02/2009:
Singleton pregnancies, with confirmed ruptured membranes from 34 weeks to 36 weeks and 6 days gestation.

Previous inclusion criteria:
Pregnant women with preterm prelabour rupture of the membranes at 34 - 36 weeks

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
Women who are in established labour, have clinical evidence of chorioamnionitis or other indications for immediate delivery such as meconium staining of the liquor or an antepartum

haemorrhage or any other contraindication to expectant management will be excluded from the study. The presence of Group B streptococcus on urine or genital tract culture will not be a specific indication for exclusion from the study.

Date of first enrolment
01/01/2005

Date of final enrolment
31/12/2013

Locations

Countries of recruitment
United Kingdom

Argentina

Australia

New Zealand

Norway

Poland

Romania

South Africa

Study participating centre
L 2, Building 52
St Leonards
Australia
NSW 2065

Sponsor information

Organisation
National Health and Medical Research Council (Australia)

ROR
https://ror.org/011kf5r70

Funder(s)

Funder type
Research council

Funder Name
National Health and Medical Research Council (Australia) (ref: ID 358378)

Alternative Name(s)
National Health and Medical Research Council, Australian Government, NHMRC National Health and Medical Research Council, NHMRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Australia

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	30/01/2016		Yes	No
Protocol article	protocol	23/03/2006		Yes	No