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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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
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.

## 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
Not available in web format, please use the contact details below to request a patient information sheet

## 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 measure
Neonatal sepsis

### Secondary outcome measures
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

### Overall study start date
01/01/2005

### 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

### Age group
Adult

### Sex
Female

### Target number of participants
1,812

### 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
Argentina

Australia

New Zealand

Norway

Poland

Romania

South Africa

United Kingdom

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

# Sponsor information

**Organisation**
National Health and Medical Research Council (Australia)

**Sponsor details**
Office of NHMRC (MDP 100)
GPO Box 9848
Canberra
Australia
2601

**Sponsor type**
Research council

**Website**
http://www.nhmrc.gov.au/

**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)**
NHMRC

**Funding Body Type**
Government organisation

**Funding Body Subtype**

National government

### Location
Australia

# 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? |
|---|---|---|---|---|---|
| Protocol article | protocol | 23/03/2006 | | Yes | No |
| Results article | results | 30/01/2016 | | Yes | No |