

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

Submission date 17/03/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 19/04/2005	Overall study status Completed	<input checked="" type="checkbox"/> Protocol
Last Edited 18/12/2017	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

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.

Study design

Randomised controlled trial

Primary study design

Interventional

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