

# Preterm Premature Rupture Of Membranes between 34 and 37 weeks: EXpectant management versus Induction of Labour 2

<b>Submission date</b> 31/01/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 07/06/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 29/12/2020	<b>Condition category</b> 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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
N/A

# Study information

## Scientific Title

The effectiveness of immediate delivery after preterm prelabour rupture of membranes between 34 and 37 weeks compared to expectant management in a multicentre randomised controlled trial

## Acronym

PPROMEXIL 2

## Study objectives

Induction of labour in patients with preterm premature rupture of membranes (PPROM) between 34 and 37 weeks' gestation will reduce the incidence of neonatal sepsis. This advantage may outweigh the effects of prematurity (e.g. respiratory distress syndrome and hypoglycaemia)

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethics committee of the University Hospital Maastricht

## Study design

Multicentre randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

Patient information sheet available in English/Dutch at [http://www.studies-obsgyn.nl/ppromexil/docs/Pat%20informatie%20PPROMEXIL%20\\_%20engelse%20versie.doc](http://www.studies-obsgyn.nl/ppromexil/docs/Pat%20informatie%20PPROMEXIL%20_%20engelse%20versie.doc) Also available in French and Turkish on request.

## Health condition(s) or problem(s) studied

Preterm prelabour rupture of membranes

## Interventions

Participants will be randomised to induction of labour or expectant management. If randomised for induction: same day or the day after. If randomised for expectant management: induction at 37 weeks' gestation. Duration of treatment: Maximum 3 weeks. The follow-up will be done after 6 weeks, 6 months and 2 years.

The analysis will be done by intention to treat. Relative risks and 95% confidence intervals will be calculated for the relevant outcome measures. The analysis will be stratified for centre and parity. In case of equivalence between outcomes, the analysis will be repeated on a per protocol basis. Quality of life as well as pain scores will be analysed using repeated measures analysis of variance. Also a cost-effectiveness analysis will be done.

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome measure**

Neonatal sepsis, measured immediately on discharge from hospital

### **Secondary outcome measures**

1. Respiratory distress syndrome (RDS)
2. Transient tachypnoea of the newborn
3. Asphyxia
4. Pneumothorax/pneumomediastinum
5. Late onset sepsis
6. Hypoglycaemia
7. Meconium aspiration syndrome
8. Necrotising enterocolitis (NEC)
9. Hyperbilirubinaemia
10. Intraventricular haemorrhage
11. Periventricular leucomalacia
12. Convulsions
13. Other neurological abnormalities and congenital abnormalities

### **Secondary maternal outcome measures:**

1. Antepartum haemorrhage
2. Umbilical cord prolapse
3. Signs of chorioamnionitis
4. Maternal sepsis
5. Thrombo-embolic complications
6. Urinary tract infection treated with antibiotics
7. Signs of endometritis
8. Pneumonia
9. Anaphylactic shock
10. Haemolysis, Elevated Liver Enzymes, Low Platelets (HELLP) syndrome
11. Death
12. Incidence of instrumental deliveries
13. Maternal quality of life
14. Maternal intervention reference
15. Costs

### **Other outcomes:**

Direct medical and non-medical costs, generated by maternal and neonatal resource utilisation during admission and post-discharge follow-up until 6 weeks after randomisation. The economic evaluation will integrate the primary clinical outcome and costs in a cost effectiveness analysis.

All outcomes will be measured immediately on discharge from hospital, and also 6 weeks and 6 months post-partum.

**Overall study start date**

01/01/2010

**Completion date**

31/12/2010

## Eligibility

**Key inclusion criteria**

1. Women presenting with preterm prelabour rupture of the foetal membranes between 34+0 and 37+0 weeks' gestation and have not delivered within 24 hours after rupture of the foetal membranes
3. Women presenting with preterm prelabour rupture of foetal membranes after 26+0 weeks gestation who have not delivered at 34+0 weeks of gestation
4. Single and multiple gestations
5. Women with child in breech presentation can also be included

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Female

**Target number of participants**

200

**Total final enrolment**

195

**Key exclusion criteria**

1. Monochorionic multiple pregnancies
2. Abnormal (non-reassuring) cardiotocogram (CTG)
3. Meconium stained amniotic fluid
4. Signs of intrauterine infection
5. Major foetal anomalies
6. Being in labour
7. Hemolytic anaemia, elevated liver enzymes and low platelet count (HELLP) syndrome
8. Severe pre-eclampsia

**Date of first enrolment**

01/01/2010

**Date of final enrolment**

31/12/2010

# Locations

## Countries of recruitment

Netherlands

## Study participating centre

De Run 4600

Veldhoven

Netherlands

5500 MB

# Sponsor information

## Organisation

Academic Medical Centre (AMC) (Netherlands)

## Sponsor details

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Amsterdam

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## Sponsor type

Hospital/treatment centre

## ROR

<https://ror.org/03t4gr691>

# Funder(s)

## Funder type

Government

## Funder Name

The Netherlands Organisation for Health Research and Development (ZonMw) (Netherlands)

# 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?
<a href="#">Other publications</a>	secondary analysis	01/09/2014		Yes	No
<a href="#">Other publications</a>	prediction model development	01/05/2014	29/12/2020	Yes	No
<a href="#">Results article</a>	results	01/10/2012	29/12/2020	Yes	No