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

Submission date	Recruitment status	[_] Prospectively registered
31/01/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/06/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
29/12/2020	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
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 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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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?
Other publications	secondary analysis	01/09/2014		Yes	No
Other publications	prediction model development	01/05/2014	29/12/2020	Yes	No
Results article	results	01/10/2012	29/12/2020	Yes	No