

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

Submission date 01/09/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 13/02/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 24/02/2015	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Study website
<http://www.studies-obsgyn/ppromexil>

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

5521

Study information

Scientific Title

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

Acronym

PPROMEXIL

Study objectives

The aim of this study is to solve the dilemma for the obstetric gynaecologist regarding the optimal treatment of women with Preterm Premature Rupture Of the Membranes (PPROM) after 34 weeks of gestation. Therefore, we will compare the effectiveness of induction of labour after PPROM between 34 and 37 weeks gestation compared to expectant monitoring on neonatal infection. Also, cost effectiveness and quality of life is measured in both treatment arms and compared.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Medical Ethical Committee of the University Hospital Maastricht, 03/03/2006, ref: MEC 05-240.5 /fh

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

Health condition(s) or problem(s) studied

Premature rupture of the membranes

Interventions

Induction of labour versus expectant management

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Neonatal sepsis

Secondary outcome measures

1. Maternal morbidity (chorioamnionitis/sepsis)
2. Respiratory Distress Syndrome (RDS)
3. Neonatal disease
4. Instrumental delivery rate
5. Quality of life and costs

Overall study start date

01/01/2007

Completion date

01/01/2010

Eligibility**Key inclusion criteria**

Pregnant women with PPRM at a gestational age from 34 + 0/7 until 37 weeks who have given informed consent.

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

520

Key exclusion criteria

1. Foetal distress
2. Major foetal anomalies
3. Meconium stained amniotic fluid
4. Maternal infection at entry
5. Monochorionic Diamniotic (MCDA) multiple pregnancy
6. Multiple pregnancy, first child breech presentation
7. Previous caesarean section
8. Diabetes mellitus (defined as use of insulin)
9. Renal disease (including Systemic Lupus Erythematosus [SLE])

- 10. Seropositive for Human Immunodeficiency Virus (HIV)
- 11. Haemolysis, Elevated Liver, Low Platelet (HELLP)/severe pre-eclampsia
- 12. Oliguria less than 500 ml/24 hours

Date of first enrolment

01/01/2007

Date of final enrolment

01/01/2010

Locations

Countries of recruitment

Netherlands

Study participating centre

P. Debijelaan 25

Maastricht

Netherlands

6202 AZ

Sponsor information

Organisation

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

Sponsor details

PO Box 93245

Den Haag

Netherlands

2509 AE

Sponsor type

Research organisation

Website

<http://www.zonmw.nl>

ROR

<https://ror.org/01yaj9a77>

Funder(s)

Funder type

Research organisation

Funder Name

The Netherlands Organisation for Health Research and Development (ZonMw) (The 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?
Protocol article	protocol	06/07/2007		Yes	No
Results article	results	01/07/2012		Yes	No
Results article	economic analysis results	01/04/2014		Yes	No
Other publications	secondary analysis	01/09/2014		Yes	No