ISRCTN29313500 https://doi.org/10.1186/ISRCTN29313500

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

Submission date	Recruitment status	[_] Prospectively registered
01/09/2006	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
13/02/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
24/02/2015	Pregnancy and Childbirth	

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 PPROM 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 (inluding 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