

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### Comparison of maternal and fetal outcomes in pregnancies with Preterm Premature Rupture of Membranes ( PPRM ) terminating in 34 th and 36 th gestational weeks : clinical trial

#### Protocol summary

##### Summary

The main etiologic factor of Preterm premature rupture of membranes ( PPRM ) before 37 weeks of pregnancy is not well understood, but early dilatation of the cervix, infection of uterus and fetus and previous preterm delivery are mentioned as the reasons for premature rupture of the amniotic sac Also several risk factors have been mentioned for PPRM .The most important risk factors are history of previous preterm rupture or endometritis , nutritional deficiency , and lower socio-economic status.PPRM has dreaded consequences for mother and fetus physiologic disturbances occurring in both of them. Maternal consequences consist of delivery complications , emergent cesarean section , corioamnionitis , endometritis, sepsis and even death .Fetal complications include preterm labor, preterm abruption , cord prolapse , respiratory distress and necrotizing enterocolitis .In this study, we are comparing maternal and fetal complication in PPRM cases with termination of 34 or 36 weeks of pregnancy .40 cases of PPRM during the study period of May 2014 to May 2015 in Tabriz Alzahra hospital and Taleghani hospital will be included .Patients will be randomized to two groups (20 each).Exclusion criteria are an underlying disease (such as hypertension , diabetes), other conditions associated with pregnancy (such as preeclampsia and eclampsia),PPROM with termination of pregnancy in the previous months , and major life-threatening fetal anomalies. Termination of pregnancy will be done at 34 weeks in group A and at 36 weeks in group B . Maternal (delivery related complications , need for emergent cesarian section , corioamnionitis, endometritis , sepsis , and maternal mortality) and fetal (preterm delivery , preterm abruption, cord prolapse , respiratory distress, and necrotizing enterocolitis) outcomes will be compared in two groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014120120168N1**  
Registration date: **2015-04-19, 1394/01/30**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2015-04-19, 1394/01/30

##### Registrant information

##### Name

Farshad Mahdavi

##### Name of organization / entity

Tabriz Medical University, General surgery

##### Country

Iran (Islamic Republic of)

##### Phone

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##### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

Research assistance of Tabriz University of Medical Sciences

##### Expected recruitment start date

2014-04-21, 1393/02/01

##### Expected recruitment end date

2015-04-21, 1394/02/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Comparision of maternal and fetal outcomes in pregnancies with Preterm Premature Rupture of Membranes ( PPRM ) terminating in 34 th and 36 th gestational weeks : clinical trial

**Public title**

Comparision of maternal and fetal outcomes in pregnancies with Preterm Premature Rupture of Membranes ( PPRM ) terminating in 34 th and 36 th gestational weeks

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Entry Requirements:Preterm Premature Rupture of Membranes recorded. Exclusion criteria: an underlying disease such as hypertension, diabetes and other conditions associated with pregnancy, such as preeclampsia and Aaklampsy , Preterm Premature Rupture of Membranes with termination of pregnancy in the other months , major life-threatening fetal anomalies

**Age**

No age limit

**Gender**

Female

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **40**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Tabriz Medical University

**Street address**

Golgasht Ave.

**City**

Tabriz

**Postal code****Approval date**

2014-06-26, 1393/04/05

**Ethics committee reference number**

5/4/2976. Code: 9348

**Health conditions studied****1****Description of health condition studied**

Preterm premature rupture of membranes

**ICD-10 code**

O60.2

**ICD-10 code description**

Preterm spontaneous labour with term delivery

**Primary outcomes****1****Description**

Maternal outcome: mortality , emergent cesarian section

**Timepoint**

Length of hospital stay

**Method of measurement**

Standard questionnaire

**2****Description**

Fetal outcome : Mortlity , Preterm Labor

**Timepoint**

Length of hospital stay

**Method of measurement**

Standard Questionnaire

**Secondary outcomes****1****Description**

Maternal outcome: Delivery related complications, Corioamnionitis,Endometritis,Sepsis - Fetal outcome: Preterm abruption,Cord prolapse, Admission to NICU, Respiratory distress, Necroziting enterocolitis

**Timepoint**

34 or 36 weeks of pregnancy

**Method of measurement**

Standard Questionnaire

**Intervention groups****1****Description**

Cesarian section surgery in 34 weeks

**Category**

Treatment - Surgery

2

**Description**

Cesarian section surgery in 36 weeks

**Category**

Treatment - Drugs

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Alzahra hospital and Taleghani hospital

**Full name of responsible person**

**Street address**

**City**

Tabriz

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Research assistance of Tabriz University of Medical Sciences

**Full name of responsible person**

Dr.Shamsi Abbasalizadeh

**Street address**

Golgasht Ave. Medical faculty

**City**

Tabriz

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Research assistance of Tabriz University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Tabriz Medical University

**Full name of responsible person**

Dr.Rana Bagheri fard

**Position**

Gynecology student

**Other areas of specialty/work**

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Tabriz Medical University

**Full name of responsible person**

Dr.Farshad Mahdavi

**Position**

General Surgeon

**Other areas of specialty/work**

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**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*