Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

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

Protocol summary

Summary

The main etiologic factor of Preterm premature rupture of mambranes (PPROM) 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 PPROM .The most important risk factors are history of previous preterm rupture or endometritis , nutritional deficiency , and lower socio-economic status.PPROM has dreaded consequences for mother and fetus physiologic disturbances occuring in both of them. Maternal consequences consist of delivery complecations , emergent cesarean section , corioamnionitis , endometritis, sepsis and even death .Fetal complecations include preterm labor, preterm abruption , cord prolapse , respiratory distress and necrotizing enterocolitis .In this study, we are comparing maternal and fetal complecation in PPROM cases with termination of 34 or 36 weeks of pregnancy .40 cases of PPROM 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 necroziting 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

+98 41 3334 7054

Email address

fmahdavi@tbzmed.ac.ir

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 (PPROM) 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 (PPROM) 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, Respitary 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 faculity
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
Street address
Artesh Ave. Alzahra hospital
City
Tabriz
Postal code
Phone
+98 41 3553 9161
Fax
Email
farshad_mahdavi@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tabriz Medical University
Full name of responsible person
Dr. Shamsi Abbasalizadeh
Position
Gynecologist - Perinatology fellowship
Other areas of specialty/work
Street address
Artesh Ave. Alzahra hospital
City
Tabriz
Postal code
Phone
+98 41 3553 9161
Fax
Email
sabbasalizadeh@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Tabriz Medical University
Full name of responsible person
Dr.Farshad Mahdavi
Position
General Surgeon
Other areas of specialty/work
Street address
Golgasht Ave. - Imam Reza Hospital
City
Tabriz
Postal code
Phone
00
Fax
Email
farshad_mahdavi@yahoo.com
Web page address

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