

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

Comparative study of the consequences of expected treatment of premature membrane rupture in women with gestational age less than 34 weeks and gestational age of 34-36 weeks

Protocol summary

Study aim

Comparative study of the consequences of expected treatment of premature membrane rupture in women with gestational age less than 34 weeks and gestational age 34-36 weeks

Design

This study is a randomized clinical trial with a parallel design and a control group that will be performed non-blinded. This is a randomized study, phase 2-3 study will be performed on 50 eligible pregnant women. Random simple is used for randomization and participants are assigned to two groups (waiting for treatment up to 36 weeks and waiting for treatment up to 34 weeks).

Settings and conduct

This study will be performed in the gynecology ward of Imam Reza Hospital in Kermanshah. The study population will include women with a definite diagnosis of premature rupture of membranes. This study is non-blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women with the final diagnosis of Premature rupture of membranes; Gestational age of 34 weeks, that up to 24 hours after rupture of the membranes having labor pains; Being at 34 to 36 weeks of gestational age waiting treatment group. Exclusion criteria: Uncertain cardiogram; Fetal major anomaly; Symptoms of intrauterine infection

Intervention groups

In waiting treatment group up to 36 weeks, they will receive 2 g of injectable ampicillin every 6 hours for the first 48 hours with oral erythromycin 400 mg every 6 hours. Five days later they will receive 500 mg amoxicillin every 8 hours and 400 mg erythromycin every 6 hours. In group waiting for treatment up to 34 weeks, they will receive 2 g of injectable ampicillin every 6 hours for the first 48 hours with oral erythromycin 400 mg every 6 hours. 5 days later they will receive 500 mg

amoxicillin every 8 hours and 400 mg erythromycin every 6 hours.

Main outcome variables

Apgar score, duration of neonatal hospitalization, respiratory distress syndrome, sepsis, Uterine bleeding

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N179**

Registration date: **2022-01-27, 1400/11/07**

Registration timing: **registered_while_recruiting**

Last update: **2022-01-27, 1400/11/07**

Update count: **0**

Registration date

2022-01-27, 1400/11/07

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

Email address

froughi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-15, 1400/10/25

Expected recruitment end date

2022-09-16, 1401/06/25
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative study of the consequences of expected treatment of premature membrane rupture in women with gestational age less than 34 weeks and gestational age of 34-36 weeks

Public title
Comparative study of the consequences of expected treatment of premature membrane rupture in women

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Women with the final diagnosis of Preterm premature rupture of the membranes (PPROM) Gestational age of 34 weeks, that up to 24 hours after rupture of the membranes having labor pains Being 34 to 36 weeks old for the waiting treatment group
Exclusion criteria:
Women with monochorionic multiple pregnancies; Uncertain cardiogram Meconium contaminated amniotic fluid Fetal major anomaly HELLP syndrome or preeclampsia Symptoms of intrauterine infection

Age
No age limit

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: 50

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be done in a simple random method, after identifying eligible persons, they will be randomly assigned a three-digit dedicated code. The last digit on the right determines the patient group. If this number is 0, 1, 2, 3, 4, it will be assigned in the first group, and if this number is 5, 6, 7, 8, 9, it will be assigned in the second group

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2021-12-11, 1400/09/20

Ethics committee reference number

IR.KUMS.MED.REC.1400.084

Health conditions studied

1

Description of health condition studied

Premature rupture of membranes

ICD-10 code

O42.90

ICD-10 code description

Premature rupture of membranes, unspecified as to length of time between rupture and onset of labor, unspecified weeks of gestation

Primary outcomes

1

Description

Apgar

Timepoint

The first and fifth minutes after birth

Method of measurement

Apgar test

2

Description

Duration of hospitalization of the infant in the intensive care unit (NICU)

Timepoint

After discharge

Method of measurement

Based on the record

3

Description

Respiratory distress syndrome

Timepoint

After birth

Method of measurement

Clinical examination

4

Description

Sepsis

Timepoint

After birth

Method of measurement

Clinical examination

5

Description

Uterine bleeding

Timepoint

after delivery

Method of measurement

Ask the patient and the doctor observation

Secondary outcomes

empty

Intervention groups

1

Description

In waiting for treatment group up to 34 weeks they will receive 2 g of injectable ampicillin every 6 hours for the first 48 hours with oral erythromycin 400 mg every 6 hours. 5 days later they will receive 500 mg amoxicillin every 8 hours and 400 mg erythromycin every 6 hours.

Category

Treatment - Drugs

2

Description

In waiting for treatment group up to 36 weeks they will receive 2 g of injectable ampicillin every 6 hours for the first 48 hours with oral erythromycin 400 mg every 6 hours. 5 days later they will receive 500 mg amoxicillin every 8 hours and 400 mg erythromycin every 6 hours.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Emam Reza Hospital

Full name of responsible person

Azadeh Falahatkar

Street address

Emam Reza Hospital, Parastar Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3427 6306

Email

azadeh.1111@yahoo.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Reza Khodarahmi

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3836 0014

Email

rkhodarahmi@kums.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kermanshah University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

Academic

Person responsible for general inquiries

Contact**Name of organization / entity**

Kermanshah University of Medical Sciences

Full name of responsible person

Azadeh Falahatkar

Position

Resident of Obstetrics and Gynecology

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Emam Reza Hospital, Parastar Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3427 6306

Email

azadeh.1111@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Maryam Zanganeh

Position

Faculty member of Kermanshah University of Medical Sciences

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Emam Reza Hospital, Parastar Boulevard

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Phone

+98 83 3427 6306

Email

mzangeneh@kums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Azadeh Falahatkar

Position

Resident of Obstetrics and Gynecology

Latest degree

Medical doctor

Other areas of specialty/work

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Email

azadeh.1111@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available