Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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Feizollah Foroughi
Name of organization / entity
kermanshah University of Medical Sciences
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Iran (Islamic Republic of)
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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 monocurion 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
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Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard
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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

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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

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

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Position

Resident of Obstetrics and Gynecology

Latest degree

Medical doctor

Other areas of specialty/work

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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