Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of azithromycin and erythromycin effect in reducing complications of preterm premature rupture of membranes: a clinical trial study

Protocol summary

Study aim
The purpose of this study was to compare the effect of azithromycin and erythromycin on pregnancy outcome in mothers with PPROM.

Design
The clinical trial, with parallel groups, double-blind, randomized, phase 1-2 on 60 patients. The rand function of Excel software was used for randomization.

Settings and conduct
Shahid Sadoughi Hospital of Yazd

Participants/Inclusion and exclusion criteria
This study will be conducted on women with a gestational age of more than 24 weeks, Women with a gestational age of less than 24 weeks, women with a cerclage, history of smoking, trauma or injury that led to PPROM, a congenital or fatal fetal anomaly, and those that consumed other antibiotics before referral, will be excluded from the study. This study will be conducted on 60 patients with PPROM after approval by the ethics committee.

Intervention groups
Group A will treat with oral azithromycin one gram single dose (n=30) and group B will treat with oral erythromycin 400 mg 4 times daily for 7 days (n=30).

Main outcome variables
Primary outcome includes latency period and chorioamnionitis. Secondary outcome includes cesarean delivery, amniotic fluid stained with meconium, postpartum endometritis and neonatal sepsis.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230129057268N1**
Registration date: **2023-02-11, 1401/11/22**
Registration timing: **registered_while_recruiting**

Last update: **2023-02-11, 1401/11/22**
Update count: **0**

Registration date
2023-02-11, 1401/11/22

Registrant information

Name
Mohadese Besharati

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-02-09, 1401/11/20

Expected recruitment end date
2023-05-20, 1402/02/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of azithromycin and erythromycin effect in reducing complications of preterm premature rupture of membranes: a clinical trial study

Public title
Comparison of azithromycin and erythromycin effect in

reducing complications of preterm premature rupture of membranes: a clinical trial study

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women with a gestational age of more than 24 weeks will be included in this study.

Exclusion criteria:

Women with a gestational age of less than 24 weeks, women with a cerclage, history of smoking, trauma or injury that led to PPROM , a congenital or fatal fetal anomaly, and those that consumed other antibiotics before referral, will be excluded from the study.

Age

No age limit

Gender

Female

Phase

1-2

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

women randomly will be divided into two groups by considering 8 random blocks of size 8 and each person in each group will receive the desired treatment.

Blinding (investigator's opinion)

Double blinded

Blinding description

Pregnant women receiving erythromycin and azithromycin regimens will be blinded.

Placebo

Not used

Assignment

Parallel

Other design features

No

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of the Shahid Sadoughi University of Medical Sciences

Street address

School of Medicine, Shahid Sadoughi University of Medical Sciences, Shohadaye gomnam Blv. Alem Square, Yazd, Iran

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Postal code

8915173143

Approval date

2022-05-11, 1401/02/21

Ethics committee reference number

IR.SSU.MEDICINE.REC.1401.047

Health conditions studied

1

Description of health condition studied

preterm premature rupture of membranes (PPROM)

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Latency period

Timepoint

The interval between the rupture of the membranes and the onset of labor

Method of measurement

Length of latency was calculated in days by subtracting the time of delivery from the time of membrane rupture.

2

Description

Clinical chorioamnionitis

Timepoint

Before delivery

Method of measurement

Clinical chorioamnionitis will be determined by clinical symptoms including fever and tachycardia and ....

3

Description

Type of delivery

Timepoint

Delivery time

Method of measurement

Observation

4

Description

Amniotic fluid with meconium

Timepoint

Before delivery

Method of measurement

Amniotic fluid stained with meconium will be determined by clinical symptoms such as fetal distress, observation of meconium discharged from amniotic fluid.

5

Description
Postpartum endometritis
Timepoint
48 to 72 hours after delivery
Method of measurement
Postpartum endometritis will be determined by the mother's fever, mother's abdominal pain, mother's unpleasant odor secretions.

6

Description
Neonatal sepsis
Timepoint
72 hours after birth
Method of measurement
Neonatal sepsis will be determined by blood culture

7

Description
Neonatal mortality
Timepoint
After delivery
Method of measurement
Observation

Secondary outcomes

empty

Intervention groups

1

Description
This study is a randomized clinical trial. group A (n=30), PPROM patients with a gestational age more than 24 weeks will treat with 1000 mg azithromycin orally as a single dose. Aditionally, they will receive intravenous ampicillin 2 g every 6 hours for 2 days and then oral amoxicillin 250 mg every 8 hours for 5 days. Then this group, will be compared with group B in terms of primary outcomes including latency period and clinical chorioamnionitis and secondary outcomes including the presence or absence of amniotic fluid stained with meconium, postpartum endometritis, and neonatal sepsis, type of delivery, condition of the newborn, weight of the newborn .
Category
Treatment - Drugs

2

Description
Intervention group: group B (n=30), PPROM patients with a gestational age more than 24 weeks will treat with 400mg erytromycin orally every 6 hour for 7 days. Aditionally, they will receive intravenous ampicillin 2 g every 6 hours for 2 days and then oral amoxicillin 250 mg every 8 hours for 5 days. Then this group, will be compared with group A in terms of primary outcomes including latency period and clinical chorioamnionitis and secondary outcomes including the presence or absence of amniotic fluid stained with meconium, postpartum endometritis, and neonatal sepsis, type of delivery, condition of the newborn, weight of the newborn.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Sadoughi Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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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
Yazd University of Medical Sciences
Proportion provided by this source
50
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
Yazd University of Medical Sciences
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Atiye Javaheri
Position
Associate Professor
Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary	Undecided - It is not yet known if there will be a plan to make this available