Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Jun 2026

Efficacy of Azithromycin versus Erythromycin to increase pregnancy length and decrease the neonatal adverse effects in premature rupture of membrane (PROM)

Protocol summary

Study aim
Comparison of the effect of Azithromycin and Erythromycin on increasing the duration of pregnancy and reducing neonatal complications in mothers with premature rupture of membranes

Design
Clinical trials with control group, with parallel, non-blind, randomized clinical trials

Settings and conduct
This study is a not blind clinical trial study that is conducted on 200 pregnant women with premature rupture of the membrane who are referred to Akbar Abadi hospital before the age of 32 weeks and who have criteria for entering the study.

Participants/Inclusion and exclusion criteria
Inclution criteria: Gestational age between weeks 24 and 32; Having informed consent to enter the study Non-inclution criteria: having hypertension; having pre-eclampsia; having congenital anomalies

Intervention groups
Control group: Ampicillin 500 mg Iv every 6 hours for the first 48 hours and Erythromycin 400, PO, every 6 hours for 7 days and Amoxicillin 500, PO, every 8 hours for 5 days after the completion of Ampicilin. Intervention group: Ampicillin 500 mg, IV, every 6 hours for the first 48 hours and Azithromycin 1mg, PO, single dose and Amoxicillin 500, PO, every 6 hours for 5 days after the completion of Ampocillin.

Main outcome variables
Duration of pregnancy ; Neonatal complication

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190601043785N1**
Registration date: **2019-08-31, 1398/06/09**
Registration timing: **registered_while_recruiting**

Last update: **2019-08-31, 1398/06/09**
Update count: **0**

Registration date
2019-08-31, 1398/06/09

Registrant information

Name
Elham Musavi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 7718 4215

Email address
omranipoor.a@tak.iums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-07-01, 1398/04/10

Expected recruitment end date
2020-12-01, 1399/09/11

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Efficacy of Azithromycin versus Erythromycin to increase pregnancy length and decrease the neonatal adverse effects in premature rupture of membrane (PROM)

Public title

"Efficacy of Azithromycin versus Erythromycin in premature rupture of membrane"

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Gestational age between weeks 24 and 32 Have informed consent to enter the study

Exclusion criteria:
having hypertension having pre-eclampsia having congenital anomalies

Age
From **15 years** old to **44 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **214**

Randomization (investigator's opinion)
Randomized

Randomization description
Individual simple randomization (alternate case) Tap/lLine

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
Ethics Committee of Iran University of Medical Sciences

Street address
No. 60, Yaghobi st., Dardasht Ave., Resalat

City
Tehran

Province
Tehran

Postal code
1651614333

Approval date
2017-12-03, 1396/09/12

Ethics committee reference number
IR.IUMS.FMD.REC 1396.9411290017

Health conditions studied

1

Description of health condition studied
Premature rupture of membranes

ICD-10 code
042.919

ICD-10 code description
Preterm premature rupture of membranes, unspecified as to length of time between rupture and onset of labor ..... unspecified trimester

Primary outcomes

1

Description
Duration of pregnancy

Timepoint
Until delivery

Method of measurement
check list

2

Description
Neonatal complications

Timepoint
From birth to discharge

Method of measurement
Baby file

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Azithromycin One gram single dose, PO, produced by Abidi factory, Ampicillin 500 mg intravenous, produced by Abidi factory, every 6 hours for 48 hours, Amoxicillin 500 mg, PO, produced by Abidi factory, every 8 hours for 5 days.

Category
Prevention

2

Description
Control group: Erythromycin 400 mg PO, produced by Abidi factory, every 6 hours for one week, Ampicillin 500 mg intravenous, produced by Abidi factory, every 6 hours for 48 hours, Amoxicillin 500 mg PO, produced by Abidi factory every 8 hours for 5 days.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Akbarabadi Hospital
Full name of responsible person
Elham Musavi
Street address
Akbarabadi Hospital., Molavi Ave
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1168743514
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Email
akbarabadihosp@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr. Shahrzad Hashemidizaji
Street address
Iran university Medical Sciences, Next to Milad Tower, Hemat Highway, Tehran
City
Tehran
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1449614535
Phone
+98 21 86701
Email
hashemidizaji.sh@iums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Elham Musavi
Position
resident
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for updating data

Contact

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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