

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Antibiotic therapy for premature rupture of membranes and maternal outcomes in sayyad shirazi hospital-Gorgan

Protocol summary

Summary

To evaluate antibiotic therapy for premature rupture of membranes and maternal outcomes in sayyad shirazi hospital-Gorgan; In this study, 140 pregnant women admitted to Sayyad Shirazi hospital with complaints runny before 34 weeks of pregnancy after ensuring rupture of membranes by examination and testing Nitrazine, will be hospitalized and recto-vaginal Group B streptococcus culture was taken from all of them and then ampicillin (2 g IV) every 6 hours and 1 g single dose of azithromycin is prescribed. After 48 hours, revealing the culture results, in a case of negative culture result they will be treated and excluded from the study. If the culture result is negative, patients are enrolled and matched according to the age of pregnancy then they divided into two groups. One of the groups treated with amoxicillin (500 mg 1 capsule every 8 hours) until one week and the other group without antibiotic treatment will be monitored. Latency period, chorioamnionitis, neonatal Apgar, birth-weight, NICU admission, IUGR incidence would be investigated in these two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017060228381N1**

Registration date: **2017-06-02, 1396/03/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-06-02, 1396/03/12

Registrant information

Name

Zanbagh Pirastehfar

Name of organization / entity

Golestan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

*Golestan University of Medical Sciences

Expected recruitment start date

2016-04-08, 1395/01/20

Expected recruitment end date

2017-03-18, 1395/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Antibiotic therapy for premature rupture of membranes and maternal outcomes in sayyad shirazi hospital-Gorgan

Public title

Antibiotic therapy for premature rupture of membranes and maternal outcomes in sayyad shirazi hospital-Gorgan

Purpose

Treatment

Inclusion/Exclusion criteria

Conditions of entry: Pregnant women with complaints of irritation between 34-24 weeks of pregnancy after ensuring rupture of membranes-by examination and testing Nitrazine; Exclusion criteria: Positive rectovaginal culture. Sample size: 140; divided into two groups of 70 pregnant woman.

Age

From **18 years** old to **41 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **140**

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

*Golestan University of Medical Sciences

Street address

5km of Gorgan-Sari road, philosophical series of Shastkola

City

Gorgan

Postal code

Approval date

2016-10-02, 1395/07/11

Ethics committee reference number

lr.goums.rec.1395.149

Health conditions studied

1

Description of health condition studied

Premature rupture of membranes

ICD-10 code

O42

ICD-10 code description

Premature rupture of membranes

Primary outcomes

1

Description

Gestational age

Timepoint

admission date with PPRM

Method of measurement

According to the first FHR sonography

Secondary outcomes

1

Description

Gestational age

Timepoint

delivery time

Method of measurement

According to the first FHR sonography

Intervention groups

1

Description

The intervention group treated with amoxicillin 500 every 8 hours a week

Category

Treatment - Drugs

2

Description

The control group without treatment oral antibiotics and monitored

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sayyad Shirazi Medical Education Center

Full name of responsible person

Zanbagh Pirastehfar

Street address

Sayyad Shirazi Medical Education Center, Gorgan, Iran

City

Gorgan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

*Golestan University of Medical Sciences

Full name of responsible person

Dr Farideh Kouchak

Street address

Beginning of the Shastkola road

City

Gorgan

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