Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

Effect of rectal Progesterone on Latent Phase Prolongation in Patients with Preterm Premature Rupture of Membranes on Neonatal and Maternal outcomes , A clinical trial study

Protocol summary

Study aim

Effect of rectal Progesterone on Latent Phase Prolongation in Patients with Preterm Premature Rupture of Membranes on Neonatal and Maternal outcomes between 26-34 weeks

Design

Clinical trial with control group, with parallel groups, randomized, phase 3 on 110 patients. Block method was used for randomization

Settings and conduct

A randomized clinical trial study was performed in Golestan province, Gorgan, Sayad Shirazi Hospital

Participants/Inclusion and exclusion criteria

Pregnant women 18-45years Fetus age between 26-34weeks based on ultrasound of the first trimester of pregnancy Diagnosis of PPROM based on observation of leakage during speculum examination, nitrazine positive test that these pregnant PPROM mothers are without labor pains.

Intervention groups

All pregnant women in the case and control groups received a seven-day course of antibiotics, including one gr oral azithromycin at the beginning of hospitalization and 2 grams of intravenous ampicillin every 6 hours for the first 48 hours of hospitalization, followed by oral amoxicillin. (500 mg every 8 hours) for 5 days after the end of 48 hours of intravenous ampicillin. In addition, pregnant women in the intervention group received 400 mg of progesterone suppository made by Abu Reihan Pharmaceutical Company once a day rectally.

Main outcome variables

Determining and comparing the latent phase; Infection; Birth weight and Apgar score and hospitalization in NICU in pregnant women with PPROM diagnosis at 26 to 34 weeks gestational age

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200610047716N1**
Registration date: **2020-08-18, 1399/05/28**
Registration timing: **retrospective**

Last update: **2020-08-18, 1399/05/28**
Update count: **0**

Registration date

2020-08-18, 1399/05/28

Registrant information

Name

Behnaz Gonabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 17 3255 4261

Email address

dr.gonabadi@goums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-22, 1398/10/01

Expected recruitment end date

2020-07-21, 1399/04/31

Actual recruitment start date

2019-12-31, 1398/10/10

Actual recruitment end date

2020-06-21, 1399/04/01

Trial completion date

2020-06-21, 1399/04/01

Scientific title
Effect of rectal Progesterone on Latent Phase Prolongation in Patients with Preterm Premature Rupture of Membranes on Neonatal and Maternal outcomes , A clinical trial study

Public title
Effect of rectal Progesterone on Latent Phase Prolongation in Patients with Preterm Premature Rupture of Membranes

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Pregnant women 18-45 years Fetus age between 26-34 weeks based on first trimester of pregnancy ultrasound PPROM diagnosis based on observation of leakage during speculum examination, nitrazine positive test that these pregnant mothers PPROM without labor pain

Exclusion criteria:
Fetus chromosomal abnormalities Abnormal biophysical profiles less than 4 Intrauterine growth restriction and weight less than ten percent according to the Alexander Growth Standard Maternal fever greater than 38 ° C Bleeding after week 24 Chorioamnionitis based on maternal criteria Type 1 diabetes Preeclampsia includes high blood pressure and proteinuria after 20 weeks of pregnancy Cervical discharge and severe obstetric medical diseases Taking corticosteroids or systemic steroids Receive antibiotics one week before hospital admission and antibiotic sensitivity

Age
From **18 years** old to **45 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **110**
Actual sample size reached: **55**

Randomization (investigator's opinion)
Randomized

Randomization description
We use the block randomization method to randomize subjects into groups that result in equal sample sizes. We use the block size 4. From the following blocks, first select 1 by accident and divide the samples into two groups according to the order and fill the blocks A for intervention and B for placebo B A B A 2) B B A A 1) B A A B 4) A B B A 3) A A B B 6) A B A B 5)

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 Golestan University of Medical Sciences

Street address
Golestan University of Medical Sciences, Gorgan,Shastkola road, Philosophical Higher Education Complex

City
Gorgan

Province
Golestan

Postal code
4934174515

Approval date
2020-08-16, 1399/05/26

Ethics committee reference number
IR.GOUMS.REC

Health conditions studied

1

Description of health condition studied
PPROM

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Increased latent phase of labor

Timepoint
From the beginning of the latent phase to the end of the latent phase

Method of measurement
Measurement of latent phase duration based on clinical examination

2

Description
neonatal Apgar score

Timepoint
Apgar score of the first and fifth minutes after birth

Method of measurement
Based on Apgar scoring criteria

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Recipients of rectal progesterone suppository 400 mg (Abu Reihan Company production), once a day
Category
Treatment - Drugs

2

Description
Control group: No therapeutic intervention
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Sayyad Shirazi Hospital
Full name of responsible person
Dr. Shohreh Vosough
Street address
Philosophical Higher Education Complex, Shast Kola Road, Gorgan
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4934174515
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+98 17 3220 2565
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shohre.007@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
Dr. Mohammad Reza Honarvar
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Philosophical Higher Education, Shast Kola Road, Gorgan
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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
Gorgan 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
Gorgan University of Medical Sciences
Full name of responsible person
Dr. Behnaz Gonabadi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for updating data

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Only part of the data, such as information about the main outcome or the like, can be shared.

When the data will become available and for how long

Start of access period 6 months after printing results

To whom data/document is available

It will be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

Use of data to complete the research process on the effects of rectal progesterone use in pregnant women with PPROM

From where data/document is obtainable

Contact the author of the article responsible for the research project data.

What processes are involved for a request to access data/document

Contact the author of the article responsible for the research project data.Specify the type of results requested.

Comments