

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of progesterone on latency period of preterm premature rupture of membrane in 24-34 weeks of gestation

Protocol summary

Summary

The main goal of this study is determining the effectiveness of progesterone on latency period of preterm premature rupture of membrane in 24-34 weeks of gestation. This is a clinical trial on 171 pregnant women with Premature rupture of membranes between 24 to 34 weeks of gestation which randomly divided into 3 groups using sequential randomization method. Inclusion criteria: obvious fluid passage or direct observation with speculum or by positive nitrazine test in gestational age of 24 to 34 week. Exclusion criteria: anomalous fetus; multiple gestation; chorioamnionitis sign; fetal distress; abruptio placenta; placenta previa; IUGR; medical diseases of mother (DM, severe preeclampsia). In first group suppository progesterone (400 mg) is given daily and in second group 17-hydroxyprogesterone (250 mg) IM is injected weekly and in last group without any medication, patients will be followed up until the end of pregnancy. All included patients will be administered betamethasone and ampicillin for 48 hours and then 500 mg amoxicillin every 8 hour and 400 mg erythromycin orally qid for 5 days. For all patients Amniotic fluid index (AFI) and sonography will be done to determine amniotic fluid volume. And all of them will be monitored for infection signs. All patients will be assessed for delivery method and fetus death in the womb and the neonates will be assessed for APGAR score of fifth minute, weight, need for NICU care and sepsis.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014020216453N1**

Registration date: **2014-03-12, 1392/12/21**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-03-12, 1392/12/21

Registrant information

Name

Syavash Moradi

Name of organization / entity

Fassa University of Medical Sciences

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s.moradi@fums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research chancellor of Kerman University of Medical Sciences

Expected recruitment start date

2012-03-20, 1391/01/01

Expected recruitment end date

2013-11-21, 1392/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of progesterone on latency period of preterm premature rupture of membrane in 24-34 weeks of gestation

Public title

Evaluation of the effect of progesterone on latency period of preterm premature rupture of membrane

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: obvious fluid passage or direct observation with speculum or by positive nitrazine test in gestational age of 24 to 34 week - according to first trimester sonography or last menstrual period. Exclusion criteria: anomalous fetus; multiple gestation; chorioamnionitis signs at the time of admission; fetal distress; abruptio placenta; placenta previa; IUGR; medical diseases of mother (DM, severe preeclampsia).

Age

From **15 years** old to **45 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **171**

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**

kerman University Medical Science

Street address

Shafa Square

City

kerman

Postal code**Approval date**

2012-07-29, 1391/05/08

Ethics committee reference number

91/266//L5

Health conditions studied**1****Description of health condition studied**

preterm premature rupture of membrane in pregnant women

ICD-10 code

O42

ICD-10 code description

Premature rupture of membranes

Primary outcomes**1****Description**

Latency period

Timepoint

from the time of rupture of membrane to delivery

Method of measurement

days from rupture of membrane to delivery

Secondary outcomes**1****Description**

Chorioamnionitis

Timepoint

during Latency period

Method of measurement

abdominal tenderness, fever, mother and fetal tachycardia and rise of WBC count

2**Description**

neonatal sepsis

Timepoint

neonatal period

Method of measurement

fever ; malaise; poor feeding; increased white blood cell ; positive blood or spinal fluid culture

3**Description**

parity

Timepoint

during the study

Method of measurement

NVD Number

4**Description**

amniotic fluid volume

Timepoint

in latency period

Method of measurement

by sonography

5**Description**

fetal death

Timepoint

in latency period

Method of measurement

The number of fetal deaths

6**Description**

age

Timepoint

in sampling period

Method of measurement

patients' age in year

7**Description**

neonatal death

Timepoint

neonatal period

Method of measurement

The number of neonatal deaths

8**Description**

Neonatal admission in intensive care unit

Timepoint

The neonatal period

Method of measurement

the number of neonatal admission

9**Description**

fifth minute apgar score

Timepoint

neonatal birth time

Method of measurement

Sum of five components OF APGAR SCORING SYSTEM

10**Description**

Delivery method

Timepoint

Delivery time

Method of measurement

sum of number of normal vaginal delivery and sum of number of cesarean delivery

Intervention groups**1****Description**

In intervention group I, 400 mg suppository progesterone (made by Aboreyhan company) is administered daily until the end of pregnancy.

Category

Treatment - Drugs

2**Description**

In intervention group II, 250 mg hydroxy progesterone (MADE BY BIOTECK COMPANY, each ampoule contains 250 mg/ml) is injected IM every week until the end of pregnancy.

Category

Treatment - Drugs

3**Description**

Control group receives no medication.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Obstetric and Gynecologic ward of Afzalipoor Hospital

Full name of responsible person

Fateme Mirzaii

Street address

Obstetric and Gynecologic ward of Afzalipoor Hospital

City

Kerman

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Research chancelor of kerman University of Medical Sciences

Full name of responsible person

Fatemeh Hassani

Street address

Tahmasbabad Square, Ebnesina Street

City

Kerman

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

Yes

Title of funding source

Research chancelor of kerman 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

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Fateme Mirzaii

Position

Gynecologist

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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