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

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Syavash Moradi
Name of organization / entity
Fassa University of Medical Sciences
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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//ل‍ک

Health conditions studied

1

Description of health condition studied
preterm premature rapture 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 ;malase;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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Person responsible for scientific inquiries

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Person responsible for updating data

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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