Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jun 2026

Evaluation of the effect of vaginal Progesterone in preventing preterm labor

Protocol summary

Summary

This is a randomized double blind clinical trial in preventing preterm labor. Inclusion criteria were: 26-36 weeks of gestation, intact membrane and confirmed preterm labor. Exclusion criteria were: disruption of treatment, lack of sufficient data and occurrence of preeclampsia. During the study course, subjects were in their 26-36 weeks of gestation with a diagnosis of preterm labor referring to Al-Zahra maternity hospital. Two hundred and sixty women were randomly assigned into the two groups. All underwent routine management of preterm labor and signed a formal consent. Subjects received either progesterone or placebo. Once a parturient was labeled as preterm, she was given a vaginal suppository. After two hours the subject was examined for cessation of labor pain. If no contraction was detected, the woman was sent to a prelabor control ward, with hydration and relative Bed Rest order. She was given a vaginal supp. per day and was discharged after 24 hours from discontinuation of contractions. They were warned against excessive physical activity and advised for prompt referral in case of labor pain. Vaginal supp should be continued till 36 weeks gestation. The aim of the study was to compare the rate of days in delay of delivery and so, maternal and neonatal complication in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138706051096N1**
Registration date: **2009-02-20, 1387/12/02**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2009-02-20, 1387/12/02

Registrant information

Name
Seyede Hajar Sharami
Name of organization / entity
Guilan University of Medical Science
Country
Iran (Islamic Republic of)
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+98 13 1322 5624
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Recruitment status

Recruitment complete

Funding source

vice chancellor for research-Guilan Universityof Medical Sciences

Expected recruitment start date

2009-01-22, 1387/11/03

Expected recruitment end date

2010-01-23, 1388/11/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of vaginal Progesterone in preventing preterm labor

Public title

Evaluation of the effect of vaginal Progesterone in preventing preterm labor

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Pregnant women were eligible to enter

the trial if 1) they were between 26-36 weeks of gestation based on their LMP or sonography before 16 weeks of gestation. 2) Confirmation of premature delivery with a)uterine contractions more than 30 seconds and three or more contractions per 30 minutes established by tochodynamometer b) cervical dilatation of 0-2 cm in nulliparous and 1 -2 cm in multiparous and cervical effacement greater than 50% 3) intact membrane. Exclusion criteria included: 1) unwillingness or inability to comply with study procedures before 36 weeks of gestation 2) lack of useful sufficient data 3) preeclampsia requiring termination of pregnancy.

Age
From **15 years** old to **50 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **260**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

1

Registry name

Secondary trial Id

Registration date
2017-11-21, 1396/08/30

Ethics committees

1

Ethics committee

Name of ethics committee
Vice chancellor for research-Guilan University of Medical Sciences

Street address
Vice chancellor for research-Guilan University of Medical Sciences-opposite of Azodi Studium-Namjo street

City
Rasht

Postal code

Approval date
empty

Ethics committee reference number
6219

Health conditions studied

1

Description of health condition studied
prevention of preterm labor

ICD-10 code
O60

ICD-10 code description
Preterm labour

Primary outcomes

1

Description
prevention of preterm labour(before 37 weeks)

Timepoint
2 hours after insertion of suppository, then weekly visit

Method of measurement
control of uterine contraction

2

Description
Prevention of preterm labor (before 34 weeks)

Timepoint
every two weeks

Method of measurement
Patient visits, uterine contraction determination

Secondary outcomes

1

Description
Delay of delivery

Timepoint
post partum

Method of measurement
documented data

2

Description
Duration of hospitalization

Timepoint
post partum (weekly)

Method of measurement
documented data

3

Description
Mean of frequancy,intensity and duration of contractions

Timepoint
48 hours after initiation of therapy

Method of measurement
detected by Tochodynamometer

4

Description
Delay of delivery
Timepoint
postpartum
Method of measurement
documented data

5

Description
Delay for a week of delivery
Timepoint
after delivery
Method of measurement
documented data

6

Description
Low birth weight
Timepoint
after delivery
Method of measurement
documented data

7

Description
APGAR score below 7
Timepoint
after delivery
Method of measurement
documented data

8

Description
NICU admission
Timepoint
after delivery
Method of measurement
documented data

9

Description
Perinatal Mortality
Timepoint
after delivery
Method of measurement
documented data

10

Description
Fetal death
Timepoint
after delivery
Method of measurement
documented data

11

Description
Neonatal distress
Timepoint
after delivery
Method of measurement
documented data

12

Description
Postpartum Retinopathy
Timepoint
after delivery
Method of measurement
documented data

13

Description
Necrotizing entrocolitis
Timepoint
after delivery
Method of measurement
documented data

14

Description
Neonatal sepsis
Timepoint
after delivery
Method of measurement
documented data

15

Description
Intraventicular hemorrhage
Timepoint
after delivery
Method of measurement
documented data

16

Description
side effects of progesteron
Timepoint
every two weeks
Method of measurement
interview

17

Description
premature rupture of membranes
Timepoint
during delivery
Method of measurement
documented data

18

Description
chorioamnionitis
Timepoint
after delivery
Method of measurement
documented data

19

Description
Severe hemorrhage (blood transfusion)
Timepoint
after delivery
Method of measurement
documented data

20

Description
Days of hospitalization
Timepoint
after delivery
Method of measurement
documented data

Intervention groups

1

Description
Intervention group: Progesterone vaginal supp (200 mg); after two hours, the subject was examined for cessation of labor pain. If no contraction was detected she was given a vaginal supp per day.
Category
empty

2

Description
Control group: Placebo vaginal supp (200 mg); after two hours, the subject was examined for cessation of labor pain. If no contraction was detected she was given a vaginal supp per day.
Category
empty

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra hospital,Rasht
Full name of responsible person
Street address
City

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research-Guilan University of Medical Sciences
Full name of responsible person
Dr. Abdolrasol Sobhani
Street address
Mellat St., Namjoo Ave.
City
Rasht
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for research-Guilan 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
Guilan University of Medical Sciences
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Dr. Seyede Hajar Sharami
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact
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Full name of responsible person
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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