Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of Preterm Labor Rate in using Proloton and Vaginal Suppository Progestrone in High Risk Pregnancies

Protocol summary

Summary

Background and aim: preterm birth is the leading cause of perinatal morbidity and mortality worldwide. The administration of progesterone and related compounds has been purposed as a strategy to prevent preterm birth. The objective of this trial was to determine comparison of preterm labor rate in high risk women for preterm labor who used 17-α-OH-p (porloton) IM and vaginal suppository progesterone. We used a randomized single blind study that included 100 high risk pregnancies for preterm labor (history of PTL, recurrent abortion , ...). Women were randomly assigned in two groups who used 17-α-OH-p (proloton) IM weekly or 100 mg of vaginal suppository for two weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201012155401N1**
Registration date: **2011-12-03, 1390/09/12**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-12-03, 1390/09/12

Registrant information

Name

Zahara Sabokro

Name of organization / entity

Hamadan university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 81 1828 0247

Email address

z.sabokro@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Hamadan university of medical sciences

Expected recruitment start date

2008-03-20, 1387/01/01

Expected recruitment end date

2011-01-02, 1389/10/12

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Preterm Labor Rate in using Proloton and Vaginal Suppository Progestrone in High Risk Pregnancies

Public title

Comparison of two drugs for Preterm Labor

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: all high risk women for pre-term labour including: recurrent abortion, pre tem labour history, cervical rippening, etc. Exclusion criteria: Epileptic and asthmatic subjects; those with uncontrolled diabetes; those who were sensitive to progesterone; those who have received progesterone four weeks before the study; mental illness; chronic HTN; active liver disorder; HIV infection or 35> CD4 count and anti-viral drug recipients; placenta previa; history of genital and breast cancer; history of thromboembolic disease and mullerian anomaly; ultrasound diagnosed major anomaly; recognized fetal chromosomal abnormalities; Multiple cerclage and preterm labor and PROM and clinical chorioamnionitis; vaginal bleeding and history of

spontaneous preterm labor without delivery (including preterm labor).

Age
From **18 years** old to **42 years** old

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Hamadan university of medical sciences

Street address
Daneshgah cross road

City
Hamadan

Postal code
24118/9/35/16/پ

Approval date
2010-05-11, 1389/02/21

Ethics committee reference number
16/35/9/24118/پ

Health conditions studied

1

Description of health condition studied
preterm labor

ICD-10 code
O60

ICD-10 code description
Preterm labour and delivery

Primary outcomes

1

Description
preterm labor

Timepoint
monthly

Method of measurement
questionnaire and physical exam

Secondary outcomes

1

Description
delivery type

Timepoint
monthly

Method of measurement
questionnaire

Intervention groups

1

Description
Intervention: 17-α-OH-p (proloton), IM, weekly

Category
Treatment - Drugs

2

Description
Control: vaginal suppository of progestrone, 100mg, daily

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Fatemie hospital

Full name of responsible person

Street address

City
Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hamadan university of medical sciences

Full name of responsible person
Dr. Heidar Tavilani

Street address
Hamadan university of medical sciences

City
Hamadan

Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Hamadan 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
Hamadan university of medical sciences
Full name of responsible person
Mehrangiz Zamani
Position
assistance
Other areas of specialty/work
Street address
Hamadan university of medical sciences
City
Hamadan
Postal code
Phone
+98 918 811 2098
Fax
Email
m.zamani@umsha.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Hamadan university of medical sciences
Full name of responsible person
Zahara Sabokru
Position
resident
Other areas of specialty/work
Street address
Hamadan university of medical sciences
City
Hamadan
Postal code
Phone
+98 912 362 8671
Fax
Email
z.sabokro@umsha.ac.ir
Web page address

Person responsible for updating data

Contact

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