

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

17-alpha-hydroxyprogesterone caproate versus vaginal progesterone suppository for the prevention of preterm birth in women with a sonographic short cervix in ARASH hospital during 2012-2013 years

Protocol summary

Summary

Objectives: To evaluate the effect of 17-alpha-hydroxyprogesterone caproate in comparison with vaginal progesterone suppository for the prevention of preterm birth in women with a sonographic short cervix. **Design:** Randomized controlled trial. **Setting and conduct:** Asymptomatic pregnant women between 16-24 weeks gestation with cervix shorter than 25 mm are being studied. **Inclusion criteria:** singleton pregnancy; gestational age between 16-24 weeks. **Exclusion criteria:** multiple pregnancy; vaginal bleeding; confirmed or suspected chorioamnionitis; having cervical cerclage; fetal abnormalities; congenital uterine abnormalities such as unicorn uterine; cervical congenital malformations such as hypoplasia of the cervix; history of cervical surgery such as conization; LEEP(loop electrical excision procedure); History of thromboembolic events; underlying disease such as uncontrolled hypertension; uncontrolled diabetes; thromboembolic disorders; heart disease and neurological – muscular disease. **Intervention:** Patients were randomly divided into two groups. In one group intramuscular dose of 250 mg 17 - alpha-hydroxyprogesterone caproate is administered once a week until the occurrence of preterm birth or complete of 36 weeks of pregnancy and in another group daily 400 mg progesterone vaginal suppository continues up to 36 weeks or until the occurrence of preterm birth. **Main outcome:** Preterm labor before 28 weeks of gestation, preterm labor between 28-34 gestational weeks and preterm labor between 34-37 gestational weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012082610664N1**

Registration date: **2012-11-06, 1391/08/16**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-11-06, 1391/08/16

Registrant information

Name

Reihaneh Pirjani

Name of organization / entity

Tehran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences Vice chancellor for research

Expected recruitment start date

2012-11-21, 1391/09/01

Expected recruitment end date

2014-03-20, 1392/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

17-alpha-hydroxyprogesterone caproate versus vaginal

progesterone suppository for the prevention of preterm birth in women with a sonographic short cervix in ARASH hospital during 2012-2013 years

Public title

17-alpha-hydroxyprogesterone caproate versus vaginal progesterone suppository for the prevention of preterm birth in women with a sonographic short cervix

Purpose

Prevention

Inclusion/Exclusion criteria

The study population consists of singleton pregnant women with gestational age of 16-24 weeks referring to ARASH hospital prenatal clinic for routine prenatal care. Exclusion criteria included multiple pregnancy; vaginal bleeding; confirmed or suspected chorioamnionitis; having cervical cerclage; fetal abnormalities; congenital uterine abnormalities such as unicorn uterine; cervical congenital malformations such as hypoplasia of the cervix; history of cervical surgery such as conization; LEEP(loop electrical excision procedure); History of thromboembolic events; underlying disease such as uncontrolled hypertension; uncontrolled diabetes; thromboembolic disorders; heart disease and neurological – muscular disease.

Age

From **14 years** old to **50 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **304**

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

Ethics committee Tehran University of Medical Sciences

Street address

Fifth Floor, Tehran University Center Building, Qods Street, Keshavarz Boulevard, Tehran

City

Tehran

Postal code

Approval date

2012-09-29, 1391/07/08

Ethics committee reference number

65961

Health conditions studied

1

Description of health condition studied

Preterm labour

ICD-10 code

O60.1

ICD-10 code description

Preterm spontaneous labour with preterm delivery
Preterm labour with delivery NOS Preterm spontaneous labour with preterm delivery by caesarean section

Primary outcomes

1

Description

Preterm labour

Timepoint

At the onset of intervention to preterm labor or to complete 37 weeks of pregnancy

Method of measurement

Gestational age at delivery occurred by weeks of age

Secondary outcomes

1

Description

neonatal hospitalization rates in NICU

Timepoint

from the birth day until one month

Method of measurement

Review neonatal file

2

Description

duration of hospitalization in NICU

Timepoint

from hospitalization until discharge

Method of measurement

Review neonatal file

3

Description

neonatal birth weight

Timepoint

after birth

Method of measurement

using neonatal scales

Intervention groups

1

Description

intramuscular dose of 250 mg 17 - alpha-hydroxyprogesterone caproate is administered once a week until the occurrence of preterm birth or complete of 36 weeks of pregnancy

Category

Treatment - Drugs

2

Description

daily 400 mg progesterone vaginal suppository continues up to 36 weeks or until the occurrence of preterm birth

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran University of Medical Sciences, ARASH Hospital

Full name of responsible person

Reihaneh Pirjani MD.

Street address

Arash Hospital, Baghdarnia Street, Farjam Street, Tehranpars , Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences Vice chancellor for research

Full name of responsible person

Akbar Fotoohi Dr.

Street address

Sixth Floor, Tehran University Center Building, Qods Street, Keshavarz Boulevard, Tehran.

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran University of Medical Sciences Vice chancellor for research

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

Tehran University of Medical Sciences

Full name of responsible person

Reihaneh Pirjani MD.

Position

Perinatologist, Assistant Professor

Other areas of specialty/work

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Hospital

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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