

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Effect of the 17 alpha hydroxy progesterone caproate in prevention of preterm labour in high risk pregnant women

Protocol summary

Summary

The objective of this study is assessment of the effect of 17 hydroxy progesterone decaproate in prevention of preterm labour. inclusion criteria include gestational age between 24_34week and exclusion criteria include cervix dilation more than 2 cm. the population under study includes high risk pregnant women with history of preterm labour congenital abnormality or acquired abnormalities of uteri, history of preterm labour in patient, her sister or mother at gestational age of 24_34 week. that come to Besat hospital in Sanandaj. sample size is 100 patient in each of two groups. all patients were assigned randomly to placebo and tried group after written consent. between 24_34 week of gestation to one group placebo and to the other group 17 hydroxy progesterone decaproate is given. every group is being assessed for labour time. the aim of this study is assessment of preterm labour in each of two groups.

General information

Acronym

PTL

IRCT registration information

IRCT registration number: **IRCT2014101019222N2**

Registration date: **2014-11-17, 1393/08/26**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-11-17, 1393/08/26

Registrant information

Name

Nazli Hamrah

Name of organization / entity

Kurdistan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 87 1328 5910

Email address

dr.nhamrah@muk.ac.ir

Recruitment status

Recruitment complete

Funding source

Kurdistan University of Medical Sciences

Expected recruitment start date

2014-10-23, 1393/08/01

Expected recruitment end date

2015-05-22, 1394/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of the 17 alpha hydroxy progesterone caproate in prevention of preterm labour in high risk pregnant women

Public title

Effect of the progesterone injection in prevention of preterm labour

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: single gestation; history of preterm labour before 37 week; history of preterm birth; history of preterm labour in sister; congenital or acquired uterine anomalies; age >18 and <45. Exclusion criteria: Hypertension; cancer; epilepsy; thromboembolic disease; asthma; age <18 and >45; IUGR; vaginal bleeding; PROM; cervical dilation >2cm; fetal major anomalies; progesterone sensitivity; not to follow up the patients;

twin pregnancy; tocolytic contraindications; uterine contraction; diabetes; history of cerclage; shortening of cervix.

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice chancellor for research Kurdistan University of Medical Sciences

Street address

Kurditan University of Medial Sciences, Pasdaran st.

City

Sanandaj

Postal code

6618634683

Approval date

2014-09-29, 1393/07/07

Ethics committee reference number

14/2688

Health conditions studied

1

Description of health condition studied

PRETERM LABOUR

ICD-10 code

O60.0

ICD-10 code description

Preterm labour without delivery

Primary outcomes

1

Description

preterm labour before of 37 weeks

Timepoint

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

Method of measurement

Patient visits, uterine contraction determination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: intramuscular dose of 250 mg 17 - alpha-hydroxyprogesterone caproate is administered once a week until the occurrence of preterm birth or complete of 34 weeks of pregnancy

Category

Treatment - Drugs

2

Description

Control group: intramuscular dose of 250 mg placebo injection is administered once a week until the occurrence of preterm birth or complete of 34 weeks of pregnancy

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat Hospital Sanandaj

Full name of responsible person

Nazli Hamrah MD

Street address

Besat Hospital, Keshavarz ST

City

Sanandaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kurdistan University of Medical Sciences

Full name of responsible person

Mr.Fardin Gharibi

Street address

Kurdistan University of Medical Sciences, Pasdaran St.

City

Sanandaj

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kurdistan 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

Besat Hospital

Full name of responsible person

Nazli Hamrah MD

Position

Resident of Obsterics & Gynecology

Other areas of specialty/work

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Full name of responsible person

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Assistant Professor

Other areas of specialty/work

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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