Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Nov 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
Kurdestan University of Medical Sciences
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Recruitment status
Recruitment complete
Funding source
Kurdestan 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 Kurdestan 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

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Sanandaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kurdestan University of Medical Sciences

Full name of responsible person
Mr.Fardin Gharibi

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Kurdestan University of Medical Sciences, Pasdaran St.

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Sanandaj

Grant name

Grant code / Reference number

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

Title of funding source
Kurdestan 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
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Resident of Obsterics & Gynecology

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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