Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

comparison of oral Dydrogesterone and 17α Hydroxyprogesterone Caproate in prevention of preterm birth in patients with preterm labor

Protocol summary

Study aim
comparison of oral Dydrogesterone and 17α Hydroxyprogesterone Caproate in prevention of preterm birth in patients with preterm labor

Design
This study is a randomized double-blind clinical trial performed on 150 pregnant women with preterm labor diagnosis and consists of control group, parallel groups

Settings and conduct
This study is conducted on pregnant women admitted to Ommol-Banin, Ghaem and Imam Reza Hospitals in Mashhad with 28 to 34 weeks of gestation and preterm labor diagnosis before 37 weeks who have cervical changes. These patients are treated with magnesium sulfate and have no contraction within 12 and no recurrence within 48 hours. In order to enter the study, patients are evaluated based on inclusion criteria.

Participants/Inclusion and exclusion criteria
Inclusion criteria: age between 18 to 35 years old, gestational age between 28 to 34 weeks, no recurrence of preterm labor 48 hours after treatment, singleton pregnancy Exclusion criteria: PROM, chorioamnionitis, severe preeclampsia, use of progesterone before entering the study, contraindications to use of progesterone, contraindications to Tocolysis, dilation of more than 4 cm, fetal anomaly, cervical cerclage, no regular use of medication

Intervention groups
Intervention group 1: Patients with gestational age up to 36 weeks and 6 days or with any delivery time less than it will receive three tablets of 10 mg Dihydrogesterone after each meal. Intervention group 2: Patients will receive a 250 mg intramuscular 17α Hydroxyprogesterone Caproate (femolife) weekly. Control group: They receive no medication.

Main outcome variables
latency period to delivery time and gestational age at birth; neonatal outcomes; birth weight; stillbirth

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20181207041879N1**
Registration date: **2019-02-24, 1397/12/05**
Registration timing: **registered_while_recruiting**

Last update: **2019-02-24, 1397/12/05**
Update count: **0**

Registration date
2019-02-24, 1397/12/05

Registrant information
Name
Fahimeh Alizadeh
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 51 3801 2755
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alizadehfh951@mums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2018-10-23, 1397/08/01
Expected recruitment end date
2019-10-23, 1398/08/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

comparison of oral Dydrogesterone and 17α Hydroxyprogesterone Caproate in prevention of preterm birth in patients with preterm labor

Public title
comparison of oral Dydrogesterone and 17α Hydroxyprogesterone Caproate in prevention of preterm birth in patients with preterm labor

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
age between 18 to 35 years old gestational age between 28 to 34 weeks (calculated based on first trimester ultrasound) no recurrence of preterm labor symptoms 48 hours after treatment singleton pregnancy no use of tobacco symptoms of preterm labor

Exclusion criteria:
Placenta Previa preterm premature rupture of membranes (PROM) Chorioamnionitis severe preeclampsia use of progesterone before entering the study contraindications to use of progesterone contraindications to Tocolysis dilation of more than 4 cm fetal anomaly uterine scar cervical cerclage uterine anomaly

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **150**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization is done by means of table of random numbers using ''www.randomization.com'' website. Numbers will be placed in sealed envelopes and once a patient enters the study, an envelope will be assigned to her based on which she will be placed in one of the 3 groups.

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 of Mashhad University of Medical Sciences

Street address
Central Building of Mashhad University of Medical Sciences (Ghorshi),Daneshgah 16, Daneshgah Street

City
Mashhad

Province
Razavi Khorasan

Postal code
9138813944

Approval date
2018-10-06, 1397/07/14

Ethics committee reference number
IR.MUMS.MEDICAL.REC.1397.378

Health conditions studied

1

Description of health condition studied
preterm labor

ICD-10 code
O60.0

ICD-10 code description
Preterm labor without delivery

Primary outcomes

1

Description
gestational age at the time of birth

Timepoint
At the time of birth

Method of measurement
Calculation of gestational age

2

Description
Apgar score at first and fifth minute

Timepoint
After child birth

Method of measurement
clinical observation

3

Description
birth weight

Timepoint
time of birth

Method of measurement
Using the scales

4

Description
stillbirth

Timepoint

at the time of birth

Method of measurement

clinical observation

5

Description

fetal weight percentiles at the time of birth based on gestational age

Timepoint

at the time of birth

Method of measurement

using scales and tape measure

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients with gestational age up to 36 weeks and 6 or with any delivery time less than it will receive three tablets of 10 mg Dihydrogesterone made by Abouryhan Pharmaceutical Company daily after each meal.

Category

Treatment - Drugs

2

Description

Intervention group: Patients will receive a 250 mg intramuscular 17α Hydroxyprogesterone Caproate (femolife), made by the Abouryhan Pharmaceuticals Company weekly.

Category

Treatment - Drugs

3

Description

Control group: No medication is prescribed.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Ommol-Banin hospital

Full name of responsible person

Masoumeh Mirteimouri

Street address

Ommol-Banin hospital, Azadi 16th, Azadi Avenue

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2

Recruitment center

Name of recruitment center

Ghaem hospital

Full name of responsible person

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3

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Fahimeh Alizadeh
Position
resident
Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
All data can be shared after patients are made unidentifiable.
When the data will become available and for how

long

Data can be accessible 6 months after results are published.

To whom data/document is available

Data will be available for researchers in universities and other scientific institutes.

Under which criteria data/document could be used

Carrying out analysis on data is permitted.

From where data/document is obtainable

Data can be accessible through sending an email to the corresponding author.

What processes are involved for a request to access data/document

After sending a request email to the corresponding author, data will be sent in 1 month.

Comments