

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### comparison of oral Dydrogesterone and 17 $\alpha$ Hydroxyprogesterone Caproate in prevention of preterm birth in patients with preterm labor

#### Protocol summary

##### Study aim

comparison of oral Dydrogesterone and 17 $\alpha$  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 17 $\alpha$  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)

##### Phone

+98 51 3801 2755

##### Email address

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 17 $\alpha$  Hydroxyprogesterone Caproate in prevention of preterm birth in patients with preterm labor

#### Public title

comparison of oral Dydrogesterone and 17 $\alpha$  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 17 $\alpha$  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

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9144663595

**Phone**

+98 51 3223 1444

**Email**

mirteimourim@mums.ac.ir

**2**

**Recruitment center**

**Name of recruitment center**

Ghaem hospital

**Full name of responsible person**

Fahimeh Alizadeh

**Street address**

Ghaem hospital, Ahmad Abad Ave

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9176699199

**Phone**

+98 51 3801 2477

**Email**

Alizadehfh951@mums.ac.ir

**3**

**Recruitment center**

**Name of recruitment center**

Imam Reza Hospital

**Full name of responsible person**

Fahimeh Alizadeh

**Street address**

Imam Reza Hospital, Imam Reza square, Ebn\_e\_sina Avenue

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9137913316

**Email**

Alizadehfh951@mums.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr Mohsen Tafaghodi

**Street address**

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

**City**

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**Province**

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**Postal code**

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**Phone**

+98 51 3841 2081

**Email**

ramresearch@mums.ac.ir

**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**

Medical doctor

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

Ghaem hospital, Ahmad Abad Ave

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9176699199

**Phone**

+98 51 3801 2477

**Email**

Alizadehfh951@mums.ac.ir

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Masoumeh Mirteimouri

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

Ommol-Banin hospital, Azadi 16th, Azadi Avenue

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

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**Phone**

+98 51 3223 1444

**Email**

mirteimourim@mums.ac.ir

**Person responsible for updating data****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Fahimeh Alizadeh

**Position**

resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

Ghaem hospital, Ahmad Abad Ave

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9176699199

**Phone**

+98 51 3801 2477

**Email**

Alizadehfh951@mums.ac.ir

**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**