

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 2026

### Effect of oral progesterone versus placebo on reducing preterm labor in women with a history of preterm labor: a double blind randomized clinical trial

#### Protocol summary

##### Summary

Objectives: To assess the effect of oral progesterone versus placebo on reducing preterm labor in women with a history of preterm labor. Design: A double blind randomized clinical trial. Setting and conduct: The eligible women with a history of preterm labor who will refer to Fatemeh Hospital during the study period will be enrolled into the trial. Inclusion criteria: Age of 18 to 25 years; gestational age of 18 to 24 weeks; at least a history of one preterm labor between 20 to 36 weeks. Exclusion criteria: Bleeding in the first trimester; abnormal fetus; active liver disease. Intervention group: Oral capsule medroxyprogesterone 100 mg twice a day until 36 weeks of pregnancy. Control group: Oral capsule placebo twice a day until 36 weeks of pregnancy. Primary outcome: Occurrence of preterm labor before 36 weeks of pregnancy by taking history. Randomization: Random assignment of the patients to the intervention and control groups through drawing of lots. Blinding: Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as double blind.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201710079014N192**  
Registration date: **2017-10-09, 1396/07/17**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-10-09, 1396/07/17

#### Registrant information

##### Name

Jalal Poorolajal

##### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 81 1838 0090

##### Email address

poorolajal@umsha.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Vice-chancellor for Research and Technology, Hamadan University of Medical Sciences

#### Expected recruitment start date

2017-01-20, 1395/11/01

#### Expected recruitment end date

2018-01-21, 1396/11/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Effect of oral progesterone versus placebo on reducing preterm labor in women with a history of preterm labor: a double blind randomized clinical trial

#### Public title

Effect of oral progesterone versus placebo on reducing preterm labor in women with a history of preterm labor

#### Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria: Age of 18 to 25 years; gestational age of 18 to 24 weeks; at least a history of one preterm labor between 20 to 36 weeks. Exclusion criteria: Bleeding in the first trimester; abnormal fetus; active liver disease.

## Age

From **18 years** old to **25 years** old

## Gender

Female

## Phase

1-2

## Groups that have been masked

*No information*

## Sample size

Target sample size: **214**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

Randomization: Random assignment of the patients to the intervention and control groups through drawing of lots. Blinding: Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as double blind.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

##### Street address

Vice-chancellor for Research the Technology,  
Hamadan University of Medical Sciences, Shahid  
Fahmideh Ave

##### City

Hamadan

##### Postal code

#### Approval date

2016-12-26, 1395/10/06

#### Ethics committee reference number

IR.UMSHA.REC.1395.377

## Health conditions studied

### 1

#### Description of health condition studied

Preterm labour

#### ICD-10 code

O60

#### ICD-10 code description

Preterm labour and delivery

## Primary outcomes

### 1

#### Description

Occurrence of preterm

#### Timepoint

Before 36 weeks of pregnancy

#### Method of measurement

By taking history

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Oral capsule medroxyprogesterone 100 mg twice a day until 36 weeks of pregnancy.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Oral capsule placebo twice a day until 36 weeks of pregnancy.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Fatemieh Hospital

##### Full name of responsible person

Dr Maryam Jamali

##### Street address

Fatemieh Hospital, Pasdaran Ave.

##### City

Hamadan

## Sponsors / Funding sources

### 1

#### Sponsor

Name of organization / entity

Vice-chancellor for Research and Technology,  
Hamadan University of Medical Sciences

**Full name of responsible person**

Dr Saeid Bashirian

**Street address**

Hamadan University of Medical Sciences, Shahid  
Fahmideh Ave

**City**

Hamadan

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice-chancellor for Research and Technology, Hamadan  
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**

Fatemieh Hospital

**Full name of responsible person**

Dr Maryam Jamali

**Position**

Resident of Gynecology

**Other areas of specialty/work**

**Street address**

Fatemieh Hospital, Pasdaran Ave.

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Fatemieh Hospital

**Full name of responsible person**

Dr Sohreh Alimohammadi

**Position**

Gynecologist

**Other areas of specialty/work**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Department of Epidemiology

**Full name of responsible person**

Dr Jalal Poorolajal

**Position**

Associate Professor

**Other areas of specialty/work**

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Medical Sciences, Shahid Fahmideh Ave

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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*