

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 May 2026

### Effectiveness of Dydrogesterone and Progesterone in prevention of preterm birth in women with a short cervix

#### Protocol summary

##### Study aim

Determining the comparative effect of dydrogesterone and progesterone in preventing premature birth in women with short cervix

##### Design

Clinical trial with control group, with parallel group, double blind, randomized, phase 3 on 64 patients. Block randomization using block of four

##### Settings and conduct

The study is conducted in Sayadshirazi Hospital, Gorgan. Patients with a minimum gestational age of 18 weeks and a cervix length of less than 25 mm are randomly classified into two groups. The dydrogesterone group (32 people) will receive oral medication, 30 mg of dydrogesterone tablets and a similar placebo suppository (glycerin suppository vaginally). The vaginal progesterone group received one 400 mg vaginal progesterone suppository and three similar oral placebo pills (vitamin B6) daily.

##### Participants/Inclusion and exclusion criteria

Entering Criteria: Cervical length less than 25 mm, measured by TVS Singleton pregnancy Refer to the center between 6 and 18 weeks of pregnancy Any evidence of threatened abortion in the first half of pregnancy Exit criteria: Multiple pregnancy Any uncontrolled systemic diseases History of consuming alcoholic beverages or drug or drug abuse Absence of gestational sac in the fifth week Lack of yolk sac in 5.5 to 6 weeks of pregnancy Absence of fetus in 6-6.5 weeks of pregnancy Absence of fetal heartbeat in weeks 16 to 24 Having a history of preterm delivery and cervical surgery Having a pair of umbilical cords confirmed by transvaginal ultrasound

##### Intervention groups

An oral dydrogesterone group will receive a daily 30 mg dydrogesterone tablet and a similar placebo suppository. The vaginal progesterone group will receive a daily 400 mg vaginal progesterone suppository and a similar placebo oral tablet.

#### Main outcome variables

Preterm labour

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20221107056426N1**

Registration date: **2022-11-14, 1401/08/23**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-11-14, 1401/08/23**

Update count: **0**

##### Registration date

2022-11-14, 1401/08/23

##### Registrant information

##### Name

mahboobeh khajepour

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 3213 1722

##### Email address

mahboobkhajepour@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-11-08, 1401/08/17

##### Expected recruitment end date

2023-11-08, 1402/08/17

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Effectiveness of Dydrogesterone and Progesterone in prevention of preterm birth in women with a short cervix

**Public title**

Effectiveness of dydrogesterone and progesterone in prevention of preterm birth in women with a short cervix

**Purpose**

Prevention

**Inclusion/Exclusion criteria****Inclusion criteria:**

Cervical length less than 25 mm, measured by transvaginal ultrasound Singleton pregnancy Refer to the center at the age of pregnancy between 6 and 18 weeks Any evidence of threatened abortion( vaginal bleeding and bloody vaginal discharge) in the first half of pregnancy Willingness and written consent to enter the study Follow-up and regular referrals for pregnancy care

**Exclusion criteria:**

Multiple pregnancy Any uncontrolled systemic disease(diabete, blood pressure, kidney, liver, etc.) History of consuming alcoholic beverages or drug or drug abuse Absence of gestational sac in the fifth week Lack of yolk sac in 5.5 to 6 weeks of pregnancy Absence of fetus in 6-6.5 weeks of pregnancy Absence of fetal heartbeat in weeks 16 to 24 Having a history of preterm delivery Having a pair of umbilical cords confirmed by transvaginal ultrasound History of surgery on the cervix Fetal and uterine anomalies

**Age**

No age limit

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider

**Sample size**

Target sample size: 64

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In order to randomize the samples, we use the block method with blocks of four. In this way, one of the following blocks is first chosen randomly (for example, with a dice) and according to the order of that, the samples are assigned to two groups. (A for the oral dydrogesterone group and B for the progesterone group (for example, if block three is selected and the first sample will be assigned to the group receiving dydrogesterone, the second and third samples will be assigned to the progesterone group, and the fourth sample will be assigned to the group receiving dydrogesterone. For the next four samples, we will randomly select a block again and perform the allocation according to it, and this process will continue until the end of the sampling.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The blinding process is done in such a way that one group receives 3 oral pills of 10 mg of Dydrogesterone and a placebo vaginal suppository similar to vaginal progesterone, and the other group receives 3 oral placebo pills similar to Dydrogesterone in terms of size, color and shape, which is a complication for the mother and does not have a fetus, they are studied by uninformed people along with vaginal progesterone

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Gorgan University of Medical Sciences

**Street address**

Central Organization of Golestan University of Medical Sciences and Healthcare Services, Hirkan Blvd, Gorgan

**City**

Gorgan

**Province**

Golestan

**Postal code**

4918936316

**Approval date**

2022-10-16, 1401/07/24

**Ethics committee reference number**

IR.GOUMS.REC.1401.348

**Health conditions studied****1****Description of health condition studied**

Preterm labour

**ICD-10 code**

O60

**ICD-10 code description**

Preterm labor

**Primary outcomes****1****Description**

Cervical length

**Timepoint**

1, 5, 9 weeks after starting treatment and immediately after delivery

**Method of measurement**

Vaginal ultrasound

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: Vaginal progesterone group, daily one suppository of 400 mg of vaginal progesterone suppository and three oral pills of the same placebo (vitamin B6)

**Category**

Prevention

**2****Description**

Control group: The oral dydrogesterone group will receive 30 mg of dydrogesterone tablets and a similar placebo suppository (vaginal glycerin suppository).

**Category**

Prevention

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Gorgan Shahid sayad shirazi hospital

**Full name of responsible person**

Mahboobeh Khajepour

**Street address**

Shahid sayad shirazi Blv

**City**

Gorgan

**Province**

Golestan

**Postal code**

4917867439

**Phone**

+98 17 3225 1502

**Email**

Mahboobkhajepour@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Gorgan University of Medical Sciences

**Full name of responsible person**

Narges beigom mirbebahani

**Street address**

Central Organization of Golestan University of Medical Sciences and Healthcare Services, Hirkan Blv, Gorgan

**City**

Gorgan

**Province**

Golestan

**Postal code**

4918936316

**Phone**

+98 17 3243 0310

**Email**

Mahboobkhajepour@gmail.com

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Gorgan 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**

Gorgan University of Medical Sciences

**Full name of responsible person**

Mahboobeh Khajepour

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

No 42, Alley 54, Shahid Mostafa Khomeini Street

**City**

Kerman

**Province**

Kerman

**Postal code**

7617657189

**Phone**

0098 43 32131722

**Email**

Mahboobkhajepour@gmail.com

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

Gorgan University of Medical Sciences  
**Full name of responsible person**  
Mahboobeh Khajehpour  
**Position**  
Resident  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Gynecology and Obstetrics  
**Street address**  
No42, Alley54, Shahid Mostafa Khomeini street  
**City**  
Kerman  
**Province**  
Kerman  
**Postal code**  
7617657189  
**Phone**  
0098 43 32131722  
**Email**  
Mahboobkhajepour@gmail.com

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Gorgan University of Medical Sciences  
**Full name of responsible person**  
Mahboobeh Khajehpour  
**Position**  
Resident  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Gynecology and Obstetrics  
**Street address**  
No 42, Alley 54, Shahid Mostafa Khomeini Street  
**City**  
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**Province**

Kerman  
**Postal code**  
7617657189  
**Phone**  
0098 43 32131722  
**Email**  
Mahboobkhajepour@gmail.com

## 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

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

### Title and more details about the data/document

Information on the main outcome

### When the data will become available and for how long

unlimited

### To whom data/document is available

unlimited

### Under which criteria data/document could be used

unlimited

### From where data/document is obtainable

mahboobkhajepour@gmail.com Dr.mahboobeh khajehpour

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

After viewing the message via email

### Comments