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 and18 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 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 khajehpour
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
Efectiveness 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 Khajehpour

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 mirbehbahani

Street address

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

City

Gorgan

Province

Golestan

Postal code

4918936316

Phone

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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 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

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

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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

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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
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