

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of the effect of progesterone suppository on reducing the rate of preterm labor in patients with uterocervical angle above 105 °

Protocol summary

Study aim

Reducing the rate of premature birth

Design

A clinical trial with a control group, with parallel groups, concentrated, phase 3 on 42 patients. For randomization, a random table of numbers is used.

Settings and conduct

Imam Khomeini Hospital, University of Tehran, patients with $UCA \geq 105^\circ$ in 18-20 weeks of gestation are randomly selected according to the table. One group was given vaginal progesterone 400 mg daily, and the other group was not given it as a drug control. CL length and UCA change rate are evaluated one month later. Finally, delivery time based on gestational age, need for cerclage, and cervical length change are compared in two groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. All women aged 18-45, 2. A singleton pregnancy carrier, 3. No history of premature birth
Exclusion criteria: 1. Having a history of premature birth, 2. History of cervical insufficiency and 3. The initial length of the cervix in the initial evaluation of the patient was $CL \leq 30\text{mm}$, 4. no consent to participate.

Intervention groups

The intervention group was given vaginal progesterone 400 mg daily from 18-20 weeks of pregnancy until 36 weeks of pregnancy, and the control group was not given medication.

Main outcome variables

Preterm delivery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190208042655N3**

Registration date: **2024-01-29, 1402/11/09**

Registration timing: **prospective**

Last update: **2024-01-29, 1402/11/09**

Update count: **0**

Registration date

2024-01-29, 1402/11/09

Registrant information

Name

Nafiseh Saedi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2298 0727

Email address

nsaedi@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-20, 1402/12/01

Expected recruitment end date

2024-08-10, 1403/05/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of progesterone suppository on reducing the rate of preterm labor in patients with uterocervical angle above 105 °

Public title

Evaluation of progesterone suppository in reducing preterm labor in high uterocervical angle

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
All women aged 18-45 A singleton pregnancy carrier No history of premature birth

Exclusion criteria:
history of preterm labor history of second-trimester abortion cervical length below 30 mm

Age
From **18 years** old to **45 years** old

Gender
Female

Phase
3

Groups that have been masked

- Data analyser

Sample size
Target sample size: **42**

Randomization (investigator's opinion)
Randomized

Randomization description
According to the table of random numbers, patients are classified into one of two intervention or control groups.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, after entering the mentioned study and filling out the informed consent form to participate in the study, and explaining the desired intervention in each group , according to the table of random numbers, the patients are placed in one of the two intervention or control groups. Finally, data analysis will be done by a third person who is completely blinded about the control and intervention groups.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Imam Khomeini Hospital Complex- Tehran University of Medical Sciences

Street address

Sattar Khan Street, Imam Khomeini Hospital Complex, Women's Department

City

tehran

Province

Tehran

Postal code

1597856511

Approval date

2023-08-29, 1402/06/07

Ethics committee reference number

IR.TUMS.IKHC.REC.1402.201

Health conditions studied

1

Description of health condition studied

preterm labor

ICD-10 code

O34.32

ICD-10 code description

Maternal care for cervical incompetence, second trimester

Primary outcomes

1

Description

The effect of progesterone suppositories in reducing premature labor

Timepoint

delivery time

Method of measurement

Investigation of preterm birth under 37 weeks of pregnancy

Secondary outcomes

1

Description

The effect of progesterone suppositories on changing the uterocervical angle one month after receiving suppositories

Timepoint

One month after receiving progesterone suppositories

Method of measurement

with Philips Affinity 70 ultrasound machine and with vaginal probe 1-10

Intervention groups

1

Description

Intervention group: Pregnant women with a uterocervical angle above 105 degrees, receive 400 mg of vaginal progesterone suppositories daily (Aborehan Company) from 18-20 weeks to 36 weeks of pregnancy.

Category

Prevention

2

Description

Control group: Pregnant women with uterocervical angle above 105 degrees and normal cervical length without

receiving medication.

Category

Prevention

Country of origin

Type of organization providing the funding

Academic

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital Complex

Full name of responsible person

Nafiseh Saedi

Street address

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Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Nafiseh Saedi

Position

assistant proffesor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr.Nima Rezaee

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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

Tehran 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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Nafise Saedi

Position

assistant proffesor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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Latest degree

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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

All data are available in SPSS file

When the data will become available and for how long

3 months after the publication of the article

To whom data/document is available

Researchers working in academic institutions

Under which criteria data/document could be used

If the data is needed and used to provide the proposal to the executor of the project, the right of the executor and the co-author of the project should be respected.

From where data/document is obtainable

Send via email nsaedi@sina.tums.ac.ir request

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

First, the reason for the request and proposal of the proposed project will be sent to nsaedi@sina.tums.ac.ir address, and then, if the executor agrees, taking into account the agreement between the parties to protect the rights of the executors of the project, it will be sent via email and in the form of SPSS file.

Comments