

# 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

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**  
Imam Khomeini Hospital Complex  
**Full name of responsible person**  
Nafiseh Saedi  
**Street address**  
sattarkhan  
**City**  
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1597856511  
**Phone**  
+98 912 747 5821  
**Email**  
saedi.tums@gmail.com

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**  
Tehran University of Medical Sciences  
**Full name of responsible person**  
Dr.Nima Rezaee  
**Street address**  
sattarkhan  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
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+98 912 747 5821  
**Email**  
nsaedi@sina.tums.ac.ir  
**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

**Country of origin**  
**Type of organization providing the funding**  
Academic

## 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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## 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**  
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**Other areas of specialty/work**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Tehran University of Medical Sciences

**Full name of responsible person**

Nafiseh Saedi

**Position**

assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

sattarkhan

**City**

Tehran

**Province**

Tehran

**Postal code**

1597856511

**Phone**

+98 21 8886 3994

**Email**

saedi.tums@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**

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**