

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### The effectiveness of the combined treatment with vaginal progesterone plus cervical pessary compared to vaginal progesterone monotherapy for the prevention of preterm birth: a randomized clinical trial.

#### Protocol summary

##### Summary

This study prospective, open-label, randomized clinical trial aimed to evaluate the effectiveness of the combined strategy of cervical pessary plus vaginal progesterone to vaginal progesterone alone in decreasing the rate of preterm birth in women with short cervical length detected by vaginal sonography in mid-pregnancy. Women were considered eligible if they had a singleton pregnancy with short cervix at 18-22 gestational weeks without any cervical dilation or medical illness. The women were randomly allocated in two groups: group A to receive 400mg of daily vaginal progesterone until 37 weeks of pregnancy, and group B to receive cervical pessary plus 400mg of daily vaginal progesterone until 37 weeks of pregnancy. Participants were visited every 4 weeks for routine assessment and detection of adverse effects of each treatment. The primary outcome measure was preterm birth before 37 weeks of gestation. The secondary outcome measures were the rate of low birth weight (LBW) delivery (defined as birth weight less than 2500 grams), premature rupture of membranes (PROM), chorioamnionitis (diagnosed based on placental pathology after delivery), requirement for NICU admission, and fetal or neonatal deaths.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201603109568N15**  
Registration date: **2016-03-22, 1395/01/03**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-03-22, 1395/01/03

#### Registrant information

##### Name

Golnaz Rezaeizadeh

##### Name of organization / entity

Maternal Fetal Neonatal Research Center, Tehran  
University of Medical Sciences, Tehran, Iran

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6119 2357

##### Email address

mfnhrc@tums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Research deputy of Tehran University of Medical  
Sciences

#### Expected recruitment start date

2014-08-01, 1393/05/10

#### Expected recruitment end date

2015-12-30, 1394/10/09

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The effectiveness of the combined treatment with vaginal progesterone plus cervical pessary compared to vaginal progesterone monotherapy for the prevention of preterm birth: a randomized clinical trial.

#### Public title

Vaginal progesterone plus cervical pessary for  
preventing preterm birth

#### Purpose

Prevention

### **Inclusion/Exclusion criteria**

Inclusion criteria: 18-40 years of age; singleton gestation; 18-22 gestational weeks; cervical length of less than 25 millimeters by transvaginal ultrasound; no cervical dilation; no history of any medical illness.

Exclusion criteria: : any medical illness upon enrollment; having urogenital infection; major fetal abnormalities; painful regular uterine contractions; placenta previa; ruptured membranes; active vaginal bleeding; history of cone biopsy; refusing to provide informed consent to participate in the study.

### **Age**

From **18 years** old to **40 years** old

### **Gender**

Female

### **Phase**

N/A

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **144**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

### **Blinding (investigator's opinion)**

Not blinded

### **Blinding description**

### **Placebo**

Not used

### **Assignment**

Parallel

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ethics Committee of the Tehran University of Medical Sciences

##### **Street address**

Tehran University of Medical Sciences, Enghelab Street.

##### **City**

Tehran

##### **Postal code**

#### **Approval date**

2010-08-20, 1389/05/29

#### **Ethics committee reference number**

10010544

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Preterm delivery

#### **ICD-10 code**

O60.1

#### **ICD-10 code description**

Preterm spontaneous labour with preterm delivery

## **Primary outcomes**

### 1

#### **Description**

preterm birth before 37 weeks of gestation

#### **Timepoint**

monthly, after the intervention, until 37th week of gestational

#### **Method of measurement**

clinical delivery and the time is assessed based on ultrasound imaging

## **Secondary outcomes**

### 1

#### **Description**

Low birth weight (LBW) delivery

#### **Timepoint**

After birth

#### **Method of measurement**

weighing scale

### 2

#### **Description**

premature rupture of membranes

#### **Timepoint**

after the intervention

#### **Method of measurement**

clinical examination

### 3

#### **Description**

chorioamnionitis

#### **Timepoint**

after the intervention

#### **Method of measurement**

diagnosed based on placental pathology after delivery

### 4

#### **Description**

requirement for NICU admission

#### **Timepoint**

after the intervention

#### **Method of measurement**

clinical examination

### 5

#### **Description**

fetal or neonatal death rate

**Timepoint**

after the intervention

**Method of measurement**

clinical examination

**Intervention groups**

**1**

**Description**

Intervention Group: Cervical pessary inserted by an obstetrician, between 18-20 weeks of gestation, in an outpatient setting. A vaginal speculum examination was done to determine the appropriate size. The site with the smallest diameter was placed upwards to surround the cervix. The patients were asked to report any vaginal or pelvic discomfort. The pessary was removed by a simple vaginal examination in the 37th week of gestation, or earlier if the patient presented with rupture of membranes, vaginal bleeding, or painful uterine contractions despite tocolytics. These patients received 400 mg of vaginal progesterone once daily before going to bed until 37th week of gestation.

**Category**

Treatment - Devices

**2**

**Description**

Control Group: Patients received 400 mg of vaginal progesterone once daily before going to bed until 37th week of gestation.

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Vali-Asr Teaching Hospital

**Full name of responsible person**

Dr. Mahdi Sheikh

**Street address**

Perinatology Clinic, Vali-Asr Hospital, Imam Khomeini Hospital Complexes, Keshavarz Blvd.

**City**

Tehran

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Maternal, Fetal and Neonatal Research Center, Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Mamak Shariat

**Street address**

Maternal, Fetal and Neonatal Research Center, Vali-Asr teaching hospital, Keshavarz Blvd.

**City**

Tehran

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Maternal, Fetal and Neonatal Research Center, Tehran 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**

Tehran University of Medical Sciences

**Full name of responsible person**

Niloofer Karbasian

**Position**

medical student

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

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Researcher  
**Other areas of specialty/work**  
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**City**

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**Postal code**  
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**Fax**  
**Email**  
**Web page address**

## 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*