

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 2026

### Comparison of Efficacy and Safety of Cervical Pessary with Routine Management in Decreasing the Preterm Labor Rate in Nulliparous Symptomatic Pregnant Women with Short Cervix: A Randomized Clinical Trial

#### Protocol summary

##### Study aim

- Evaluation of the Efficacy of Cervical Pessary in Decreasing the rate of preterm labor in women with singleton pregnancy and shortened cervix - Evaluation of Safety of Cervical Pessary in Decreasing the rate of preterm labor in women with singleton pregnancy and shortened cervix

##### Design

A two parallel arm groups randomized clinical trial, without placebo, without blinding and concealment, with sample size of 100

##### Settings and conduct

Study was performed in a referral teaching hospital with annual census of 40,000. Included women were randomly allocated to 2 groups after verifying that the cervical length is  $<25$  mm yet. In first group (pessary group), a cervical pessary (Milex® Pessary, CooperSurgical co, NewYork, USA) with proper size was placed for patient in lithotomy position. In second group (control group), no pessary was inserted and patients received only the routine standard institutional treatments.

##### Participants/Inclusion and exclusion criteria

- We included patients with gestational age between 24 weeks and 0 days to 34 weeks and 0 days and shortened cervical length ( $\leq 25$  mm measured by transvaginal ultrasound scan in second trimester) -We excluded cases with major fetal abnormalities, fever or any other clinical findings in favor of chorioamnionitis, placenta previa; women with normal cervical length and women who had not responded to the routine standard treatments of preterm labor and were experiencing continued signs and symptoms of preterm labor after 48 hours of admission, vaginal bleeding, signs of ruptured membranes.

##### Intervention groups

Cervical Pessary Insertion

##### Main outcome variables

Primary outcome: giving birth after 37 weeks of gestation Secondary outcome: - possible side effects of pessary (including vaginal discharge, pessary descent, urinary tract infection, severe pelvic pain or discomfort) - spontaneous preterm birth before 34 weeks

#### General information

##### Reason for update

Due to a miscalculation in conversion of Hijri to Gregorian date, the recruitment dates were entered wrongly so they are updated.

##### Acronym

-

##### IRCT registration information

IRCT registration number: **IRCT20180819040830N3**  
Registration date: **2020-04-29, 1399/02/10**  
Registration timing: **prospective**

Last update: **2020-11-20, 1399/08/30**

Update count: **1**

##### Registration date

2020-04-29, 1399/02/10

##### Registrant information

###### Name

Zahra Naeiji

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 5506 2628

###### Email address

z.naeigi@sbmu.ac.ir

##### Recruitment status

**Recruitment complete****Funding source****Expected recruitment start date**

2020-05-01, 1399/02/12

**Expected recruitment end date**

2020-10-01, 1399/07/10

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of Efficacy and Safety of Cervical Pessary with Routine Management in Decreasing the Preterm Labor Rate in Nulliparous Symptomatic Pregnant Women with Short Cervix: A Randomized Clinical Trial

**Public title**

Role of Cervical Pessary in Prevention of Preterm Labor

**Purpose**

Prevention

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

Gestational age between 24 weeks and 0 days to 34 weeks and 0 days Shortened cervical length (defined as cervical length  $\leq$ 25 mm measured by trans-vaginal ultrasound scan in second trimester)

**Exclusion criteria:**

Major fetal abnormalities Fever or any other clinical findings in favor of chorioamnionitis and Placenta previa Women with normal cervical length Women who had not responded to the routine standard treatments of preterm labor and were experiencing continued signs and symptoms of preterm labor after 48 hours of admission Vaginal bleeding Signs of ruptured membranes.

**Age**From **18 years** old**Gender**

Female

**Phase**

N/A

**Groups that have been masked***No information***Sample size**Target sample size: **100****Randomization (investigator's opinion)**

Randomized

**Randomization description**

Computer generated blocks of 4 in block randomization method

**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, Shahid Beheshti University of Medical Sciences

**Street address**

Mahdiye hospital, Shishegar Khaaneh St., Fadayian Eslam Blv.

**City**

Tehran

**Province**

Tehran

**Postal code**

1445763693

**Approval date**

2017-09-21, 1396/06/30

**Ethics committee reference number**

IR.SBMU.RETECH.REC.1396.460

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

preterm labor

**ICD-10 code****ICD-10 code description****Primary outcomes****1****Description**

Giving birth after 37 weeks of gestation

**Timepoint**

At delivery time

**Method of measurement**

Number of weeks and days between first day of the last menstrual period and day of delivery

**Secondary outcomes****1****Description**

Possible side effects of pessary (including vaginal discharge, pessary descent, urinary tract infection, severe pelvic pain or discomfort)

**Timepoint**

From pessary insertion to delivery

**Method of measurement**

history taking and physical examination

## 2

### **Description**

Delivery before 34 weeks of gestation

### **Timepoint**

At labor

### **Method of measurement**

Number of weeks and days between first day of last menstrual period and day of delivery

## **Intervention groups**

### 1

#### **Description**

Intervention group: insertion of a cervical pessary (Milex® Pessary, CooperSurgical co, NewYork, USA) with proper size

#### **Category**

Treatment - Devices

### 2

#### **Description**

Control group: routine care

#### **Category**

Treatment - Devices

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Mahdieh Hospital

##### **Full name of responsible person**

Dr Zahra Naeiji

##### **Street address**

Mahdieh Hospital, Shoosh Sq.

##### **City**

Tehran

##### **Province**

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##### **Postal code**

1185817311

##### **Phone**

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##### **Fax**

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##### **Email**

mahdieh\_hospital@sbmu.ac.ir

##### **Web page address**

<https://mmc.sbmu.ac.ir/>

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Shahid Beheshti University of Medical Sciences

##### **Full name of responsible person**

Afshin Zarghi

##### **Street address**

Araabi St., Yaman Av., Chamran highway

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1215765432

##### **Phone**

+98 21 23871

##### **Email**

Mpajouhesh@sbmu.ac.ir

##### **Grant name**

##### **Grant code / Reference number**

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

Yes

##### **Title of funding source**

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

##### **Full name of responsible person**

Zahra Naeiji

##### **Position**

Assistant Professor

##### **Latest degree**

Specialist

##### **Other areas of specialty/work**

Gynecology and Obstetrics

##### **Street address**

Shishe gar Khaneh St., Fadayian Eslam blv., Shossh Sq.

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##### **Phone**

+98 21 5506 2628

##### **Email**

zahranaeiji1398@yahoo.com

## **Person responsible for scientific**

## **inquiries**

### **Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Zahra Naeiji

**Position**

assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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## **Person responsible for updating data**

### **Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Zahra Naeiji

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assistant professor

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## **Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

"There is no further information"

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available