

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 (≤ 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: routin 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

Tehran

Postal code

1185817311

Phone

+98 21 5506 2628

Fax

+98 21 5506 2628

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.

City

Tehran

Province

Tehran

Postal code

1445663693

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

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City

Tehran

Province

Tehran

Postal code

1445763693

Phone

+98 21 5506 2628

Email

zahrabahman77@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Zahra Naeiji

Position

assistant professor

Latest degree

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Province

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+98 21 5506 2628

Email

zahranaeiji98@yahoo.com

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