

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparative assessment of ring pessary and cervical cerclage for preterm birth in twin pregnancies

Protocol summary

Study aim

Since there is no available previous study on the preference of cerclage or pessary to prevent preterm delivery in twin pregnancies, this study aims to do comparative assessment of the prevalence of preterm delivery in twin pregnancy using these two methods.

Design

This phase 3 clinical trial study was performed on 50 twin pregnant women referring to Tehran Taleghani hospital through years from 2017 to 2019 with cervical length less than 25 mm, which are assigned randomly to two groups of 25, using cerclage (control) and pessary (intervention), and the ratio of the incidence of preterm delivery in both groups is examined and compared

Settings and conduct

We will conduct a randomized trial comparing pessary placement with cerclage in women who have twin pregnancy and have a cervical length of 25 mm or less at 14 weeks to 24 weeks and 6 days of gestation. Both groups will receive treatment with vaginal progesterone. The study will be carried out in Taleghani Hospital, Tehran, Iran.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Twin pregnant women referring to Tehran Taleghani hospital from 2017 to 2019 with cervical length less than 25 mm in the 14th week after measurement by TVS. It is noteworthy to say that all women will receive progesterone. Exclusion criteria: Women with high parity, uterine anomalies, chronic diseases such as rheumatoid diseases, kidney failure, diabetes, recurrent abortion, women over 40 and under 18 years old, history of preterm delivery, history of previous serology, neonatal death and painful uterine contractions.

Intervention groups

pessary placement vs. cerclage in women who had twin pregnancy and had a cervical length of 30 mm or less at 14 weeks to 24 weeks and 6 days of gestation

Main outcome variables

Maternal age; Preterm labor; Pregnancy number; Fetal sex

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170724035265N2**

Registration date: **2018-02-23, 1396/12/04**

Registration timing: **registered_while_recruiting**

Last update: **2018-02-23, 1396/12/04**

Update count: **0**

Registration date

2018-02-23, 1396/12/04

Registrant information

Name

Nazanin Hajizadeh

Name of organization / entity

Shahid Beheshti University of Medical Sciences and Health Services

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Do not have funds

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2019-03-21, 1398/01/01

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative assessment of ring pessary and cervical cerclage for preterm birth in twin pregnancies

Public title
Comparative assessment of ring pessary and cervical cerclage for preterm birth in twin pregnancies

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Twin pregnant women referring to Tehran Taleghani hospital from 2017 to 2019 with cervical length less than 25 mm in the 14th week after measurement by TVS All women will receive proluton. All women aged from 18 to 40
Exclusion criteria:
All women with multiparity, uterus anomaly, chronic disease (RA, CRF, DM, RPL) All women aged more than 40 and under 18 All women with preterm labor delivery, prior cerclage, IUFD, uterus painful contraction

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: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization method is simple randomizing with permutable blocks sized one. Randomization unit is individual. Randomizing tool is SPSS software..

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 Shahid Beheshti University of Medical Sciences and Health Services

Street address

Shahid Arabi Street,Next to Shahid Beheshti University of Medical Sciences,Yemen Street,Velenjak,Chamran highway,

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Approval date

2017-09-08, 1396/06/17

Ethics committee reference number

IR.SBMU.MSP.REC.1396.468

Health conditions studied

1

Description of health condition studied

Pereterm Delivery

ICD-10 code

O60.1

ICD-10 code description

Preterm spontaneous labour with preterm delivery

Primary outcomes

1

Description

Maternal age

Timepoint

Weekly

Method of measurement

Transvaginal Sonography (TVS)

Secondary outcomes

empty

Intervention groups

1

Description

Twin pregnancies with cervical length shorter than 25 mm, using pessary to prevent preterm delivery.

Category

Treatment - Devices

2

Description

Control group: Twin pregnancies with cervical length shorter than 25 mm, using ceclage to prevent preterm delivery

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleqani Hospital

Full name of responsible person

Nazanin Hajizadeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Deputy of Shahid Beheshti University of
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Full name of responsible person

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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

Research Deputy of Shahid Beheshti University of
Medical Sciences and Health Services

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 and
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Full name of responsible person

Nazanin Hajizadeh

Position

Resident of Obstetrics and Gynecology

Latest degree

Medical doctor

Other areas of specialty/work

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Full name of responsible person

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

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

Undecided - It is not yet known if there will be a plan to
make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to
make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to
make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to
make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to
make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to
make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to
make this available