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

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Recruitment status

Recruitment complete

Funding source

Research deputy of Tehran University of Medical Scienses

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, untill 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 Scienses

Full name of responsible person

Niloofar Karbasian

Position

medical student

Other areas of specialty/work

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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