

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effectiveness of daily rectal progesterone to prevent preterm delivery

Protocol summary

Study aim

Determine the effectiveness of daily rectal progesterone to prevent preterm delivery

Design

Double blind, randomized controlled clinical trial with parallel groups

Settings and conduct

The study was conducted as a double blind clinical trial in Akbar Abadi Educational Hospital on pregnant women with gestational age of 26 to 34 weeks, 4 uterine contractions within 20 minutes or 8 within 60 minutes, cervical dilatation of 1 cm and more, and cervical effacement of more than 50%. Participants, the main investigator and those who evaluate the outcome were blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: gestational age of 26 to 34 weeks, 4 uterine contractions within 20 minutes or 8 within 60 minutes, cervical dilatation of 1 cm and more, and cervical effacement of more than 50%. Exclusion criteria: ruptured membrane, vaginal bleeding, fetal death, fetal distress and intrauterine growth restriction (IUGR).

Intervention groups

In the intervention group, micronized progesterone(Tasnim Pharmaceutical Company, Tehran, Iran.) 200 mg daily for up to 36 weeks as rectal and in the control group, placebo(Tasnim Pharmaceutical Company, Tehran, Iran.) was prescribed rectally for up to 36 weeks each day.

Main outcome variables

Gestational age at delivery; delivery below 37 weeks.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20091023002624N28**

Registration date: **2018-11-30, 1397/09/09**

Registration timing: **retrospective**

Last update: **2018-11-30, 1397/09/09**

Update count: **0**

Registration date

2018-11-30, 1397/09/09

Registrant information

Name

Maryam Kashanian

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 7752 3487

Email address

maryamka@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2018-04-21, 1397/02/01

Actual recruitment start date

2016-04-20, 1395/02/01

Actual recruitment end date

2018-04-21, 1397/02/01

Trial completion date

2018-04-21, 1397/02/01

Scientific title

The effectiveness of daily rectal progesterone to prevent preterm delivery

Public title

The effect of progesterone to prevent preterm delivery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
 Gestational age of 26 to 34 weeks Four contractions within 20 minutes or 8 contractions within 60 minutes
 Cervical dilatation of 1 cm and more Cervical effacement of more than 50%

Exclusion criteria:
 Ruptured membrane Vaginal bleeding Fetal death Fetal distress and intrauterine growth restriction History of trauma Cervical dilatation of 4 cm and more Systemic disorders Preeclampsia Known uterine abnormalities Smoking Any drug abuse Poly hydramnious & oligo hydramnious Fetal abnormalities Any suspicious intrauterine infection Previous use of tocolitic in present pregnancy Blood pressure lower than 90/50 mmHg Women who continue to have a pregnancy are dangerous to them

Age
 No age limit

Gender
 Female

Phase
 2-3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
 Target sample size: **140**
 Actual sample size reached: **142**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Eligible women were randomly assigned into two groups of drug and placebo. Randomization was performed using sealed envelopes. Participants selected an envelope with letters A, B, C, D written. Envelopes A and C received the medication and envelopes B and D received the placebo.

Blinding (investigator's opinion)
 Double blinded

Blinding description
 The researcher, patients and those who evaluate the outcome were not aware of the allocation of study groups. Participants selected an envelope with letters A, B, C, D written. Envelopes A and C received the medication and envelopes B and D received the placebo. The researcher was not aware of the assignment of letters. The placebo was completely similar to rectal progesterone and was prepared by the same factory.

Placebo
 Used

Assignment
 Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Hemmat Highway, Chamran Cross

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2016-11-22, 1395/09/02

Ethics committee reference number

IR.IUMS.REC 1395.9311290015

Health conditions studied

1

Description of health condition studied

Preterm labour and delivery

ICD-10 code

O60

ICD-10 code description

Preterm labour and delivery

2

Description of health condition studied

Preterm labour without delivery

ICD-10 code

O60.0

ICD-10 code description

Preterm labor without delivery

3

Description of health condition studied

Preterm spontaneous labour with preterm delivery

ICD-10 code

O60.1

ICD-10 code description

Preterm spontaneous labour with preterm delivery

4

Description of health condition studied

Preterm spontaneous labour with term delivery

ICD-10 code

O60.2

ICD-10 code description

Preterm spontaneous labour with term delivery

Primary outcomes

1

Description

Gestational age at delivery

Timepoint

Date of delivery

Method of measurement

File

2

Description

Delivery under 37 weeks

Timepoint

Date of delivery

Method of measurement

File

Secondary outcomes

1

Description

Neonatal weight

Timepoint

At birth

Method of measurement

File

Intervention groups

1

Description

Intervention group: Micronized progesterone(Tasnim Pharmaceutical Company, Tehran, Iran.) 200 mg daily was administered rectally for up to 36 weeks of gestation.

Category

Treatment - Drugs

2

Description

Control group: Placebo(Tasnim Pharmaceutical Company, Tehran, Iran.) was administered rectally for up to 36 weeks of gestation.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Akbarabadi Hospital

Full name of responsible person

Maryam Kashanian

Street address

Molavi Ave., Molavi Cross, Baghe Ferdows Station.

City

Tehran

Province

Tehran

Postal code

1168743514

Phone

+98 21 5563 3244

Email

akbarabadihosp@yahoo.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Seyyed Kazem Malakouti

Street address

Hemmat Highway, Chamran Cross

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 86701

Email

PR@iums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Maryam Kashanian

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Molavi Ave., Molavi Cross, Baghe Ferdos Station.

City

Tehran

Province

Tehran

Postal code

1168743514

Phone

+98 21 5563 3244

Email

maryamkashanian@yahoo.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Maryam Kashanian

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Molavi Ave., Molavi Cross, Baghe Ferdos Station.

City

Tehran

Province

Tehran

Postal code

۱۱۶۸۷۴۳۵۱۴

Phone

+98 21 5563 3244

Email

maryamkashanian@yahoo.com

Person responsible for updating data**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Maryam Kashanian

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Molavi Ave, Molavi Cross, Baghe Ferdos Station.

City

Tehran

Province

Tehran

Postal code

1168743514

Phone

+98 21 5563 3244

Email

maryamkashanian@yahoo.com

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