Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 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
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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
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Molavi Ave., Molavi Cross, Baghe Ferdows Station.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Seyyed Kazem Malakouti
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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
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
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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