

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Aug 2026

The Effect of Oral Vs Vaginal Misoprostol on The Duration of Induction of First Labor

Protocol summary

Study aim

Comparison of the effect of Oral and Vaginal Misoprostol on the Duration of First Labor Induction

Design

This study is a randomized, parallel-group clinical trial in which pregnant women who were candidates for induction were assigned to two groups: oral and vaginal misoprostol. Randomization was performed in a block design and there was no possibility of blinding participants or providers.

Settings and conduct

In this study, term pregnant mothers who were candidates for labor induction and who were eligible for the study were admitted to Afzalipour Hospital in Kerman. The randomization sequence was generated by a statistician using computer-generated random numbers with variable blocks (4 and 6) and an allocation ratio of 1:1. To conceal allocation, opaque, sealed, and numbered envelopes were used sequentially, and when each patient arrived, the next envelope was opened in order and the intervention group was determined.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Term pregnancy (Less than or equal to 37 weeks of gestation), Bishop Score Less Than or Equal To 6, First Birth of a Pregnant Mother Exclusion criteria: Pregnant Women with Contraindications to Vaginal Delivery, Abnormal Fetal Heart Rate Pattern, Vaginal Bleeding, and Women with Known Hypersensitivity to Misoprostol or Prostaglandin Analogs.

Intervention groups

Group A: Misoprostol 50 micrograms (Abu Raihan Pharmaceutical) Tablet Orally Every 6 Hours Until Reaching a Bishop Score of More Than 8 or a Maximum Dose of Misoprostol 200 micrograms or the Onset of Active Labor and Cervical Effacement; Group B: Misoprostol 25 micrograms Tablet Vaginally Every 6 Hours Until Reaching a Bishop Score of More Than 8 or A Maximum Dose of Misoprostol 200 µg or the Onset of Active Labor and Cervical Effacement

Main outcome variables

Time from Intervention to Natural Birth

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250513065720N1**

Registration date: **2025-10-20, 1404/07/28**

Registration timing: **registered_while_recruiting**

Last update: **2025-10-20, 1404/07/28**

Update count: **0**

Registration date

2025-10-20, 1404/07/28

Registrant information

Name

Zohreh Salari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3132 8306

Email address

zohreh_salari@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-08-22, 1404/05/31

Expected recruitment end date

2026-01-19, 1404/10/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Oral Vs Vaginal Misoprostol on The Duration of Induction of First Labor

Public title

The Effect of Oral and Vaginal Misoprostol on the Duration of first Labor Induction

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Term Pregnancy (Less than or Equal to 37 weeks of Gestation) with a Singleton is Estimated based on the LMP Criterion (if Regularly and Reliably Confirmed by a Specialist Physician) or Ultrasound. Bishop Score Less than or Equal to 6 Cephalic Presentation of the fetus Having an Intact Membrane Reactivity of the Non-Stress Test Amniotic fluid volume less than 5 Estimated Fetal Weight less than 4000 Grams First Birth of a Pregnant Mother

Exclusion criteria:

Pregnant women with contraindications to vaginal delivery Chorioamnionitis HIV positivity Previous uterine surgery Abnormal fetal heartbeat pattern Vaginal Bleeding and Women with Known Hypersensitivity to Misoprostol or Prostaglandin Analogues

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

The Present Study Will be a Randomized Clinical Trial Study. The Statistical Population of this Study will be Pregnant Mothers in Their First Trimester Who are Candidates for Labor Induction and Who Refer to Afzalipour, Kerman. The Random Allocation Sequence will be Generated by an Independent Statistician Using Computer-Generated Random Numbers (Blockrand Package in R Software) with Variable Block Sizes of 4 and 6, in a 1:1 Ratio (Oral Misoprostol : Vaginal Misoprostol). Allocation Concealment will be Ensured Using Prepared By The Statistician, Who Is Not Involved in Patient Enrolment or Treatment. Participant Enrolment will be Carried out by the Attending Physician or Midwife, who will open The next Envelope in Sequence at the Time of Enrolment to Determine Group Allocation. Due to the Nature of the Interventions, Blinding of Participants and Care Providers is not Feasible; However, Outcome Assessors and Data Analysts Will Remain Blinded to Group Allocation.

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**

Research Ethics Committees of Afzalipour Hospital- Kerman University of Medical Sciences

Street address

Afzalipour Hospital, Emam Khomeini Blv.

City

Kerman

Province

Kerman

Postal code

7616913355

Approval date

2025-04-29, 1404/02/09

Ethics committee reference number

IR.KMU.AH.REC.1404.022

Health conditions studied**1****Description of health condition studied**

Childbirth

ICD-10 code

O75.8

ICD-10 code description

Other specified complications of labor and delivery

Primary outcomes**1****Description**

Time from Intervention to Natural Birth

Timepoint

From the time of the first dose of Misoprostol to the delivery of the Baby

Method of measurement

Clinical Record, Physical Examination

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group 1: Misoprostol 50 Microgram Tablets (Mizotec Tablets, Abu Rayhan Pharmaceutical Company) Orally Every 6 Hours Until Reaching a Bishop Score of more than 8 or a Maximum Misoprostol Dose of 200 Micrograms or the Onset of Active Labor and Cervical Dilatation.

Category

Treatment - Drugs

2

Description

Intervention Group 2: Misoprostol 25 Microgram Tablet (Mizotec Tablets, Abu Raihan Pharmaceutical Company) Vaginally Every 6 Hours Until Reaching a Bishop Score of More than 8 or a Maximum Misoprostol Dose of 200 Micrograms or the Onset of the Active Phase of Labor and Cervical Dilatation.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipour Hospital

Full name of responsible person

Maryam Toghrali

Street address

Afzalipour Hospital, Emam Khomeini Blv.

City

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Province

Kerman

Postal code

7616913355

Phone

+98 34 3132 8000

Email

dr.maryamtoghrali@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Hamid Sharifi

Street address

Ebn-e-Sina St.,Jahad Blvd., Kernan

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Phone

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m.sharifi7996@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Maryam Toghrali

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Maryam Toghrali

Position

Resident

Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for updating data

Contact
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Full name of responsible person
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Position
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is Potentially Shareable after De-Identifying Individuals.

When the data will become available and for how long

starting 6 Months after Publication

To whom data/document is available

People Working in Academic Institutions

Under which criteria data/document could be used

With Previous Agreement with the Corresponding Author

From where data/document is obtainable

Corresponding Author, Email Address

What processes are involved for a request to access data/document

Email Address

Comments