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)
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+98 34 3132 8306
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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.
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7616913355
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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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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 updating data

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Position
Resident
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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