Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Aug 2026

Evaluation and Comparison of the Effect of Vaginal and Oral Misoprostol for Cervical Ripening in Post-term Primigravida Mothers

Protocol summary

Study aim
Comparison of Vaginal and Oral Misoprostol for Cervical Ripening in Post-term Primigravida Mothers

Design
A clinical trial with two different intervention groups, utilizing a parallel group design, non-blinded, randomized, phase 3 study involving 80 patients. Randomization was performed using Random Allocation Software.

Settings and conduct
The study is in the field of obstetrics and gynecology, conducted at Shariati Hospital in Bandar Abbas. It involves the administration of misoprostol via two routes, vaginal and oral, in post-term primigravida mothers who present to the hospital.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Post-term primigravida mothers who have referred to Shariati Hospital in Bandar Abbas and have voluntarily agreed to participate in the study. Exclusion Criteria: Presence of spontaneous uterine contractions Previous uterine surgery Oligohydramnios Placenta previa Intrauterine Growth Restriction (IUGR) Requirement for cesarean section Umbilical cord prolapse Unexplained vaginal bleeding Contraindications to the administration of prostaglandins Contraindications to labor induction Presence of renal or hepatic disease Uncontrolled epilepsy Allergy Intolerance

Intervention groups
Intervention Group 1: Administration of 50 micrograms of oral misoprostol every 3 to 6 hours, up to a maximum of 6 doses. Intervention Group 2: Administration of 25 micrograms of vaginal misoprostol every 3 to 6 hours, up to a maximum of 6 doses.

Main outcome variables
The Bishop score, which is a scoring system used to evaluate the readiness of the cervix for natural labor. A Bishop score above 7 indicates a high readiness of the cervix for labor.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20240519061844N1**
Registration date: **2025-06-14, 1404/03/24**
Registration timing: **prospective**

Last update: **2025-06-14, 1404/03/24**
Update count: **0**

Registration date
2025-06-14, 1404/03/24

Registrant information
Name
Nastaran Taherpour
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-06-22, 1404/04/01
Expected recruitment end date
2026-03-20, 1404/12/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

Evaluation and Comparison of the Effect of Vaginal and Oral Misoprostol for Cervical Ripening in Post-term Primigravida Mothers

Public title
Effect of Oral and Vaginal Misoprostol
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Post-term primigravida mothers who have voluntarily agreed to participate in the study and have referred to Shariati Hospital in Bandar Abbas
Exclusion criteria:
Presence of spontaneous uterine contractions Previous uterine surgery Oligohydramnios Placenta previa Intrauterine Growth Restriction (IUGR) Cesarean section Umbilical cord prolapse Unexplained vaginal bleeding Contraindications to the administration of prostaglandins Contraindications to labor induction Presence of renal or hepatic disease Uncontrolled epilepsy Allergy Intolerance
Age
No age limit
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization Method: Simple randomization. Participants are randomly assigned to one of the two intervention groups (oral or vaginal). This process is carried out using statistical software. Unit of Randomization: Individual. Each post-term primigravida mother is independently assigned to one of the intervention groups. Randomization Tool: Random Allocation Software. No Need for Allocation Concealment: Given the design and objectives of the study, allocation concealment is not necessary, and the allocation of participants to the groups is done transparently
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 Hormozgan University of Medical Sciences
Street address
Chamran Blvd., Hormozgan University of Medical Sciences
City
Bandar Abbas
Province
Hormozgan
Postal code
7916613885
Approval date
2025-03-17, 1403/12/27
Ethics committee reference number
IR.HUMS.REC.1403.410

Health conditions studied

1

Description of health condition studied
Post-term
ICD-10 code
O48.0
ICD-10 code description
Post-term pregnancy

Primary outcomes

1

Description
Bishop Score
Timepoint
Baseline (before intervention): The Bishop score is measured at the baseline before the administration of the first dose of misoprostol.4 hours after each dose: The Bishop score is measured 4 hours after the administration of each dose of misoprostol to monitor initial changes in cervical ripening.8 hours after each dose: The Bishop score is measured 8 hours after the administration of each dose of misoprostol to track changes in cervical ripening.Finally, after achieving a Bishop score of 7 or after 6 doses: The Bishop score is measured either after achieving a score of 7 or after the administration of up to 6 doses of misoprostol, whichever occurs first.
Method of measurement
Cervical dilation: Measured in centimeters using clinical examination by a specialist physician.Cervical effacement: Percentage of cervical thinning determined by clinical examination by a specialist physician.Cervical position: Position of the cervix (posterior, mid, anterior) assessed by clinical examination by a specialist physician.Cervical consistency: Softness, medium, or firmness of the cervix determined by clinical examination by a specialist physician.Fetal station: Position of the fetal head relative to the cervix assessed by clinical

examination by a specialist physician.

Secondary outcomes

empty

Intervention groups

1

Description
first Intervention group: Substance Name: Misoprostol Chemical Composition and Concentration: Misoprostol, Prostaglandin E1 analog Dosage: 50 micrograms Frequency of Administration: Every 3 to 6 hours, up to a maximum of 6 doses Duration of Administration: Until achieving a Bishop score of 7 or administration of up to 6 doses Route of Administration: Oral
Category
Treatment - Drugs

2

Description
Second Intervention group: first Intervention group: Substance Name: Misoprostol Chemical Composition and Concentration: Misoprostol, Prostaglandin E1 analog Dosage: 25 micrograms Frequency of Administration: Every 3 to 6 hours, up to a maximum of 6 doses Duration of Administration: Until achieving a Bishop score of 7 or administration of up to 6 doses Route of Administration: Vaginal
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shariati Hospital
Full name of responsible person
Nastaran Taherpour
Street address
Shahid Naser Blvd.
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7914964157
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bandare-abbas University of Medical Sciences
Full name of responsible person
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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
Bandare-abbas 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
Bandare-abbas University of Medical Sciences
Full name of responsible person
Nastaran Taherpour
Position
OB & GYN Resident
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for scientific inquiries

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Person responsible for updating data

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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
Undecided - It is not yet known if there will be 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
The shared materials will include de-identified individual participant data focusing on primary outcomes, along with essential study documents such as the full study protocol and data analysis plan. Only data pertinent to the primary outcomes will be shared.

When the data will become available and for how long
Data and associated documents will be made accessible beginning six months after publication of the study results and will remain available for a period of five years.

To whom data/document is available
Access will be granted primarily to academic and research institution-affiliated investigators. Requests from industry professionals will be considered on a case-by-case basis.

Under which criteria data/document could be used
The shared data may only be used for scientific and academic research purposes. Applicants must agree to perform analyses strictly according to the approved study protocol, maintain participant confidentiality, and obtain additional ethical approval for any use beyond the original scope.

From where data/document is obtainable
Applicants seeking access to the data should contact the Data Access Coordinator at the Research Center of Bandar Abbas Shariati Hospital. Additionally, for requested information, they may contact the project supervisor, Dr. Nastaran Taherpoor, via email at nst94@yahoo.com

What processes are involved for a request to access data/document
Applicants must submit a formal request outlining their research objectives and data analysis plan. Upon review and approval of these requests, the data and associated documents will be provided to the applicants.

Comments