Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effects and possible side effects of oral misoprostol 100 and 50 in patients with a body mass index above 30 for labor induction in term and post-term pregnancies

Protocol summary

Study aim

A study to evaluate and compare the effects and potential complications of different doses of misoprostol (100 micrograms and 50 micrograms) for labor induction in pregnant women with a body mass index (BMI) above 30 at term and post-term gestation.

Design

Phase 3, single-blind (for patients), evaluator-blinded, randomized controlled trial with parallel groups, conducted on 92 patients (46 per group). Block randomization was performed using random number generation software.

Settings and conduct

This single-center clinical trial was conducted in the Obstetrics Department of Shahid Akbarabadi Educational Hospital on 92 patients with BMI > 30 to compare two vaginal misoprostol doses of 50 and 100 micrograms. Obstetric outcomes and complications were evaluated with 24-hour monitoring. The study employed a single-blind design for patients and assessors.

Participants/Inclusion and exclusion criteria

Gestational age 37-42 weeks BMI ≥ 30 Indication for induction of labor Favorable cervical status (Bishop Score ≥ 5) Singleton pregnancy Cephalic presentation Signed informed consent

Intervention groups

Randomized clinical trial with a parallel design, comprising two intervention groups: Low-dose group (50 mcg vaginal misoprostol) Standard-dose group (100 mcg vaginal misoprostol) Objectives: To compare the efficacy and safety of two different doses of misoprostol for labor induction in pregnant women with BMI > 30. To evaluate outcomes including time to delivery, mode of delivery, and adverse effects. Characteristics: Vaginal administration with dose repetition based on a standardized protocol. Close clinical monitoring for 24 hours. Sample size: 92 patients (46 per group) using block randomization method.

Main outcome variables

Duration of labor; rate of successful vaginal delivery; incidence of uterine hyperstimulation; maternal side effects; infant status

General information

Reason for update

Acronym

MIS100/50-OBE

IRCT registration information

IRCT registration number: **IRCT20250811066824N1**
Registration date: **2025-09-04, 1404/06/13**
Registration timing: **prospective**

Last update: **2025-09-04, 1404/06/13**
Update count: **0**

Registration date

2025-09-04, 1404/06/13

Registrant information

Name

Sheyda Sheli

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 8670 2604

Email address

dr.sheyda.sheli@gmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2025-09-23, 1404/07/01

Expected recruitment end date

2026-09-22, 1405/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects and possible side effects of oral misoprostol 100 and 50 in patients with a body mass index above 30 for labor induction in term and post-term pregnancies

Public title

Comparison of the Efficacy and Safety of Oral Misoprostol 100 µg versus 50 µg for Labor Induction in Term and Post-Term Pregnancies in Obese Women (BMI ≥ 30): A Randomized Controlled Trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Pregnancy Status: Pregnant women at 37 to 41 weeks of gestation (term and post-term pregnancy). Body Mass Index (BMI): Have a BMI greater than 30. Indication for Induction: Have a medical indication for induction of labor with misoprostol.Health Status: Be in good general health (as determined by medical history and clinical judgment). No Contraindications: Have no known contraindications to the use of misoprostol (e.g., no history of previous cesarean delivery or major uterine surgery in this context*).

Exclusion criteria:

Any medical or obstetric conditions that make the use of misoprostol dangerous (e.g., prior cesarean delivery, multiple gestation, placental problems, etc.). The patient’s unwillingness to participate in the study or to sign informed consent. Any known allergy or sensitivity to misoprostol.

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

In this clinical trial, after confirming eligibility and obtaining informed consent, participants will be randomized to one of two intervention groups: the intervention group receiving a dose of 100 micrograms of misoprostol and the group receiving a dose of 50 micrograms of misoprostol. Randomization mechanism: to ensure balanced distribution of characteristics (including age, parity, BMI, etc.) between the two groups and to reduce selection bias, block randomization will be used with a random number generator software (such as SPSS or Random.org). Generation of allocation sequence: The random allocation sequence will be generated prior to the study by a colleague who is not involved in recruitment or intervention (an independent randomization unit) with variable and concealed block sizes. Allocation concealment: to prevent selection bias, the generated allocation sequence will be stored in sealed, sequentially numbered envelopes or in a secure online system so that the treating physician and the patient are unaware of the next group assignment. Allocation: after final eligibility confirmation for enrollment, the treating physician will determine the group assignment for that patient by opening the sequential envelope or accessing the online system.

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 Iran University of Medical Sciences

Street address

Vice Chancellor for Research and Technology, Central Headquarters Building, Iran University of Medical Sciences, Next to Milad Tower, Hemmat Highway, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2025-08-05, 1404/05/14

Ethics committee reference number

IR.IUMS.FMD.REC.1404.292

Health conditions studied

1

Description of health condition studied

Labor Induction in Pregnant Women with Obesity (Body Mass Index BMI ≥ 30).

ICD-10 code

O61.0

ICD-10 code description

Failure of induction of labor

Primary outcomes

1

Description
The time interval, measured in hours, from the administration of the first dose of misoprostol to the complete birth of the baby.
Timepoint
The exact time of the first dose administration and the time of birth will be meticulously recorded in the clinical reports. The difference between these two times will be calculated.
Method of measurement
This variable is the most direct indicator for assessing the efficacy of the intervention (different doses of misoprostol). A shorter duration indicates a higher efficacy of the drug dose in accelerating the labor process.

2

Description
The proportion of deliveries concluded vaginally without requiring surgical intervention (cesarean section) to the total number of deliveries in each group, reported as a percentage.
Timepoint
The mode of delivery (vaginal or cesarean) will be recorded for each patient in the research dataset.
Method of measurement
This outcome measures the ultimate goal of labor induction. A higher rate in one group indicates the superiority of that intervention in achieving a lower-risk, physiological birth.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Received misoprostol 50 micrograms vaginally.Method of administration: A 100-microgram misoprostol tablet is divided into two halves, and one half (50 micrograms) is administered.Dosage protocol: Administer every 4 to 6 hours based on the patient's clinical response (maximum of 4 doses in 24 hours).Monitoring: Continuous CTG monitoring and recording of adverse effects (uterine hyperstimulation, fever, nausea).
Category
Treatment - Drugs

2

Description
Control group: Administer misoprostol 100 mcg vaginally. Method of administration: Administer one 100 mcg tablet whole. Dosage protocol: Administer every 4 to 6 hours based on the patient's clinical response (maximum of 4 doses in 24 hours). Monitoring: Continuous CTG monitoring and record adverse events (uterine hyperstimulation, fever, nausea).
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
shahid akbar abadi hospital
Full name of responsible person
Sheida Sheli
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Central Headquarters Building, Iran University of Medical Sciences, Next to Milad Tower, Hemmat Highway, Tehran, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
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Vice Chancellor for Research and Technology, Central Headquarters Building, Iran University of Medical Sciences, Next to Milad Tower, Hemmat Highway, Tehran, Iran.
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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
50

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
Sheida Sheli

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Gynecology and Obstetrics

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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
De-identified Individual Participant Data (IPD) will be shared via public research data repositories (such as Zenodo, Figshare, or Mendeley Data) under an Open Access license after the completion of the study and the publication of the primary results. The data will be provided in Excel or CSV format, accompanied by a README file containing variable descriptions and

definitions.

When the data will become available and for how long

Immediately following publication of the primary manuscript: Study Protocol Statistical Analysis Plan (SAP) Informed Consent Form (de-identified version) Clinical Study Report (based on CONSORT guidelines) Within a maximum of 12 months after study completion: De-identified Individual Participant Data (IPD) Analysis Scripts/Codes Data Dictionary

To whom data/document is available

Open Access (Public): Study Protocol Clinical Study Report (after publication) Statistical Analysis Plan (SAP) Informed Consent Form (de-identified version) Conditions: These documents will be made publicly available with full open access through public repositories (such as Open Access journals or data repositories).

Under which criteria data/document could be used

Mandatory Citation: Any use of the data or documents requires proper citation of the primary published article from this study. Non-Commercial Use Only: The data may only be used for non-commercial, academic, and research purposes. Any commercial use is strictly prohibited without prior written permission from the principal investigators. Purpose Transparency: Requesters must transparently explain the specific purpose and intended use of the data in their application. Research Ethics Compliance: Users must commit to using the data in accordance with Helsinki Ethical Principles and all other relevant guidelines. Privacy Protection: Any attempt to re-identify participants or use the data outside the pre-defined framework is strictly forbidden.

From where data/document is obtainable

Iranian Registry of Clinical Trials (www.irct.ir) The journal publishing the article (contingent on article acceptance)

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

1. Submission of Initial Request: The requester must send a formal written request in English or Persian to the principal investigator's email address (research@iums.ac.ir). This request must include the following: Specific purpose for using the data (e.g., conducting a meta-analysis, study validation, educational purposes). Description of the proposed research plan. Requester's organizational affiliation. Written commitment to adhere to ethical principles and cite the primary study. 2. Initial Review by the Access Committee: The request will be reviewed by the Data Access Committee (comprising the principal investigators and the ethics monitor). Review criteria: Alignment of the request's purpose with ethical principles. Requester's technical and scientific capability to use the data responsibly. No conflict with the interests of the participants or the principal investigators. This stage will take a maximum of 4 weeks. 3. Signing of the Data Transfer Agreement (DTA): If the request is approved, the requester must sign a Data Transfer Agreement (DTA). DTA content includes: Commitment to non-commercial use. Prohibition of any attempt to re-identify participants. Obligation to cite the primary article. Reporting the results of data analyses to the principal investigators. 4. Delivery of Data/Documents: Data will be provided in standard formats (e.g., CSV, SPSS, PDF) via secure platforms (such as encrypted email or FTP). Accompanying documentation includes: Data Dictionary (variable definitions). Statistical Analysis Plan. User guide (README file). 5. Post-Delivery Monitoring: The requester is obligated to provide an annual progress report on the use of the data. Any publication or report based on the data must be approved by the principal investigators prior to publication.

Comments