Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Aug 2026

A comparative study of the effectiveness and side effects of buccal and vaginal misoprostol in labor induction

Protocol summary

Study aim
A comparative study of the effectiveness and side effects of buccal and vaginal misoprostol in labor induction

Design
This is a randomized, unblinded clinical trial with a parallel design. This randomized study will be conducted on 42 candidate mothers to receive misoprostol. A random block is used for randomization and the participants are assigned to three intervention groups.

Settings and conduct
This study, which will be conducted in Imam Reza Hospital in Kermanshah city, is blinded. All mothers in this group are subjected to continuous fetal heart rate monitoring one hour before induction and one hour after, and after the onset of uterine contractions until delivery, they will be constantly monitored.

Participants/Inclusion and exclusion criteria
Inclusion criteria: monogamous; Pregnancy above 37 weeks; bishop's score less than/equal to 4; Cephalic presentation; live fetus, The weight of the fetus is less than 4 kilograms and the amniotic fluid index is more than 5 Exclusion criteria: Mothers who have contraindications for taking misoprostol

Intervention groups
The first intervention group of vaginal misoprostol will receive 25 micrograms of misoprostol (manufactured by Aria Pharmaceutical Company) vaginally. The second intervention group will receive 25 micrograms of buccal misoprostol (between teeth and cheek mucosa). The third intervention group will receive 50 micrograms of buccal misoprostol (between teeth and cheek mucosa). In cases where Bishop's score did not change after 6 hours or appropriate uterine contractions (three contractions of more than 40 seconds in 10 minutes) did not occur, the next dose of misoprostol will be repeated and this process will continue for 24 hours.

Main outcome variables
Duration of labor, nausea, fever, chills

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130812014333N209**
Registration date: **2023-08-27, 1402/06/05**
Registration timing: **prospective**

Last update: **2023-08-27, 1402/06/05**
Update count: **0**

Registration date
2023-08-27, 1402/06/05

Registrant information

Name
Feizollah Foroughi

Name of organization / entity
kermanshah University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-09-11, 1402/06/20

Expected recruitment end date
2024-05-09, 1403/02/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A comparative study of the effectiveness and side effects of buccal and vaginal misoprostol in labor induction

Public title
Study of the effectiveness and side effects of buccal and vaginal misoprostol in labor induction

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Monogamous Pregnancy above 37 weeks bishop's score less than/equal to 4 Cephalic presentation live fetus The weight of the fetus is less than 4 kilograms and the amniotic fluid index is more than 5

Exclusion criteria:
Mothers who have contraindications for taking misoprostol (active cardiopulmonary disease, history of previous cesarean section, or history of major uterine surgery such as myomectomy and uterine reconstruction surgery).

Age
No age limit

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **42**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization using the blocking method with blocks in sizes 6 and 9. For randomization, the site https://www.sealedenvelope.com is used. All codes are recorded on paper and stored in specific envelopes. Each of the generated codes is kept separately inside the envelope and the secretary gives one of these envelopes to the patient before the patient enters the doctor's room. Accordingly, the next patient code is not predictable. The doctor determines which treatments to perform based on the patient's code. Only the physician performing the intervention will be aware of the code assigned to the patient. After evaluating the outcome, based on the patient's name, the collected information will be linked to the assigned code.

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 Kermanshah University of Medical Sciences

Street address
Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard

City
Kermanshah

Province
Kermanshah

Postal code
6715847141

Approval date
2023-05-28, 1402/03/07

Ethics committee reference number
IR.KUMS.MED.REC.1402.135

Health conditions studied

1

Description of health condition studied
labour induction

ICD-10 code
O61

ICD-10 code description
Failed induction of labor

Primary outcomes

1

Description
Duration of labor

Timepoint
End of study

Method of measurement
Based on the time measured from induction of labor to final delivery

2

Description
nausea

Timepoint
During the study

Method of measurement
Ask the patient

3

Description
fever

Timepoint
During the study

Method of measurement

Using a thermometer

4

Description
chills
Timepoint
During the study
Method of measurement
Ask the patient

Secondary outcomes

empty

Intervention groups

1

Description
The first intervention group of vaginal misoprostol will receive 25 micrograms of misoprostol (manufactured by Aria Pharmaceutical Company) vaginally.
Category
Treatment - Drugs

2

Description
The second intervention group will receive 25 micrograms of buccal misoprostol (between teeth and cheek mucosa).
Category
Treatment - Drugs

3

Description
The third intervention group will receive 50 micrograms of buccal misoprostol (between teeth and cheek mucosa).
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza Hospital
Full name of responsible person
Mahdis Akrami
Street address
Emam Reza Hospital, Parastar Boulevard
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Dr. Cyrus Jalili
Street address
Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti Boulevard
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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
Kermanshah 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
Kermanshah University of Medical Sciences
Full name of responsible person
Mahdis Akrami
Position
Resident of Obstetrics and Gynecology
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for scientific inquiries

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Member of the academic staff of Kermanshah University of Medical Sciences
Latest degree
Specialist
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is no further information
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available