Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jul 2026

Safety and efficacy of cervical administration of misoprostol in induction of labor in mothers with unripe cervix and term pregnancy compared to vaginal and sublingual administration: a randomized clinical trial.

Protocol summary

Study aim
Comparing the effect of cervical misoprostol with vaginal and sublingual misoprostol in induction of labor in mothers with unripped cervix and term pregnancy.

Design
A randomized, single-blind clinical trial with three parallel groups on 123 people. Stratified block randomization is done using Sealedenvelop.com software.

Settings and conduct
The study will be conducted in the delivery ward of Akbarabadi Hospital. Eligible patients, after obtaining informed consent, will undergo induction of labor by prescribing misoprostol by one of the three intracervical, sublingual, or vaginal routes (41 people in each group). Maternal and neonatal outcomes will be evaluated. The outcome assessor and data analyzer were blinded to the assigned groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Women aged 18-40 years old, singleton pregnancy with appropriate weight and Bishop score less than or equal to 6. Exclusion criteria: high-risk pregnancies.

Intervention groups
Intervention group with intracervical misoprostol, sublingual misoprostol, and vaginal misoprostol,

Main outcome variables
Time to reach active labor phase, time lag to delivery and neonatal Apgar

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200421047152N4**
Registration date: **2023-10-11, 1402/07/19**
Registration timing: **prospective**
Last update: **2023-10-11, 1402/07/19**
Update count: **0**

Registration date
2023-10-11, 1402/07/19

Registrant information

Name
Arash Mohazzab

Name of organization / entity
Avicenna Research Institute

Country
Iran (Islamic Republic of)

Phone
+98 21 2351 9630

Email address
amohazzab@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-10-17, 1402/07/25

Expected recruitment end date
2024-03-10, 1402/12/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Safety and efficacy of cervical administration of misoprostol in induction of labor in mothers with unripe cervix and term pregnancy compared to vaginal and sublingual administration: a randomized clinical trial.

Public title
Safety and efficacy of cervical administration of

misoprostol in induction of labor compared to vaginal and sublingual administration

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women aged 18-40 years Singleton pregnancy Cephalic presentation Gestational age more than 37 weeks Appropriate pelvic examination Intact membranes Fetal weight between 90-10th percentile estimated by ultrasound ishop score less than or equal to 6

Exclusion criteria:

Birth history equal to or more than 3 Blood pressure equal to or greater than 140/90 mmHg Proteinuria or preeclampsia Getational diabetes Unreliability of fetal heart trace or any fetal distress Polyhydramnios or oligohydramnios The possibility of fetal macrosomia Intrauterine fetal death Previous history of uterine surgery Bleeding Placenta previa

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **123**

Randomization (investigator's opinion)

Randomized

Randomization description

The candidates will be allocated into groups in a stratified randomization method (based on the history of parity) with a permutation block of 6 using a randomization list generated by the Sealedenvelope.com website software. The randomly generated sequence will be placed one by one in opaque closed envelopes and after writing the codes on it, it will be given to the third person in the delivery block, and will be opened after the entry of each volunteer and the group of that person will be specified.

Blinding (investigator's opinion)

Single blinded

Blinding description

Study outcomes will be assessed by someone other than the intervention assignor. The information of the three groups will be provided to the statistical analyst in coded form so that they are not aware of the intervention groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

IUMS Biomedical Research Ethics Committee

Street address

Next to Milad Tower, Hemmat

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2022-11-23, 1401/09/02

Ethics committee reference number

IR.IUMS.REC.1402.604

Health conditions studied

1

Description of health condition studied

Labour induction

ICD-10 code

O61

ICD-10 code description

Failed induction of labour

Primary outcomes

1

Description

Time to reach active labour phase

Timepoint

Immediately after intervention

Method of measurement

Physical examination

Secondary outcomes

1

Description

Time to delivery

Timepoint

Between intervention and delivery

Method of measurement

Clinical examination

2

Description

Percentage of cesarean section

Timepoint

24 hours after intervention

Method of measurement

Clinical assessment

3

Description
Neonatal apgar
Timepoint
First and fifth minutes after delivery
Method of measurement
clinical assessment

Intervention groups

1

Description
Intervention group with intracervical misoprostol: In this group, 25 micrograms of intracervical misoprostol is prescribed to induce labor. If appropriate contractions are not reached, misoprostol is repeated with the same dose every four hours. This process continues until at least three contractions with adequate strength with a duration between 40-60 seconds occur within ten minutes or four doses of misoprostol are repeated.
Category
Treatment - Drugs

2

Description
Intervention group: Intervention group with sublingual misoprostol: In this group, 25 micrograms of sublingual misoprostol is prescribed to induce labor. If appropriate contractions are not reached, misoprostol is repeated with the same dose every four hours. This process continues until at least three contractions with adequate strength with a duration between 40-60 seconds occur within ten minutes or four doses of misoprostol are repeated.
Category
Treatment - Drugs

3

Description
Intervention group: Intervention group with vaginal misoprostol: In this group, 25 micrograms of vagianl misoprostol is prescribed to induce labor. If appropriate contractions are not reached, misoprostol is repeated with the same dose every four hours. This process continues until at least three contractions with adequate strength with a duration between 40-60 seconds occur within ten minutes or four doses of misoprostol are repeated.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Akbarabadi hospital
Full name of responsible person
Dr. Nooshin Eshraghi
Street address
Bagh ferdous station, Molavi St.
City
Tehran
Province
Tehran
Postal code
1168743514
Phone
+98 21 5560 6034
Fax
+98 21 5560 8012
Email
eshraghi.n@iums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Reza Falak
Street address
Next to Milad Tower, Hemat Highway
City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Phone
+98 21 86701
Email
falak.r@iums.ac.ir
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
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
Iran University of Medical Sciences
Full name of responsible person

Nooshin Eshraghi
Position
Associated professor
Latest degree
Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Bagh ferdous station, Molavi St.
City
Tehran
Province
Tehran
Postal code
1168743514
Phone
+98 21 5560 6034
Email
eshraghi.n@iums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Nooshin Eshraghi
Position
Associated professor
Latest degree
Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Bagh ferdous station, Molavi St.
City
Tehran
Province
Tehran
Postal code
1168743514
Phone
+98 21 5560 6034
Email
eshraghi.n@iums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Iranian academic center for education culture and research
Full name of responsible person
Arash Mohazzab
Position
PhD
Latest degree
Specialist
Other areas of specialty/work
Epidemiology
Street address
Yakhchal Junction, Shariati street
City
Tehran
Province
Tehran
Postal code
1941913114
Phone
+98 21 2351 9630
Fax
Email
amohazzab@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be 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
Not applicable
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available