Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Nov 2026

Comparison of the safety and effectiveness of labor induction using 25 micrograms of oral Misoprostol versus 50 micrograms in pregnant women with premature rupture of membranes

Protocol summary

Study aim

The safety and effectiveness of labor induction with 25 micrograms of misoprostol compared to 50 micrograms of misoprostol in women with premature rupture of membranes are investigated. According to the study results, a specific protocol for the delivery room of Shahid Akbarabadi Hospital will be developed.

Design

Patients are divided into two groups by easy sampling method.

Settings and conduct

Pregnant women referred to Shahid Akbarabadi Hospital who have full-term singleton pregnancies are included in the study from the beginning of 2022 to 2023. After confirming premature rupture of fetal membranes, in the absence of contraindications for natural delivery and contraindications for misoprostol administration, they will be placed in one of the two treatment groups of 25 micrograms and 50 micrograms of oral Misoprostol.

Participants/Inclusion and exclusion criteria

36 weeks pregnancy or more. Premature rupture of the membranes is confirmed by the amniotic fluid method or clear discharge. Bishop scores less than 4. Live singleton pregnancy. Parity less than 5. No history of cesarean delivery. Cephalic presentation. Absence of contraindications for natural childbirth. Absence of contraindications for prescribing misoprostol.

Intervention groups

Patients are divided into two groups, the first group receives 25 micrograms of oral misoprostol every 2 hours up to 12 doses and the second group receives 50 micrograms of oral misoprostol every 4 hours up to 6 doses.

Main outcome variables

The rate of occurrence of vaginal delivery, instrumental delivery, and cesarean delivery, the interval from induction of labor to birth, the incidence rate of chorioamnionitis, uterine tachysystole, amniotic fluid infection, neonatal outcomes including newborn Apgar score, intensive care unit admission, newborn death, need for antibiotic prescription and umbilical cord blood gases

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221123056587N1**
Registration date: **2023-07-27, 1402/05/05**
Registration timing: **retrospective**

Last update: **2023-07-27, 1402/05/05**
Update count: **0**

Registration date

2023-07-27, 1402/05/05

Registrant information

Name

Erfane Ebadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3447 2205

Email address

erfane91@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-21, 1400/01/01

Expected recruitment end date

2023-03-21, 1402/01/01

Actual recruitment start date
2021-03-21, 1400/01/01
Actual recruitment end date
2023-03-21, 1402/01/01
Trial completion date
2023-03-21, 1402/01/01

Scientific title
Comparison of the safety and effectiveness of labor induction using 25 micrograms of oral Misoprostol versus 50 micrograms in pregnant women with premature rupture of membranes

Public title
Comparison of the safety and efficacy of labor induction with oral Misoprostol in different doses
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Pregnant women with premature rupture of membranes No history of cesarean delivery No Contraindication of natural labor No Contraindication to Misoprostol Cephalic presentation Parity less than 5 Bishop Score of less than 4 Singleton pregnancy Pregnant for 36 weeks or more
Exclusion criteria:
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
4
Groups that have been masked
No information
Sample size
Target sample size: **400**
Actual sample size reached: **400**
Randomization (investigator's opinion)
N/A
Randomization description
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 School Medicine - Iran University of Medical Sciences
Street address
Milad Tower International Conference Center Street, Hemmat Highway, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2021-06-19, 1400/03/29
Ethics committee reference number
IR.IUMS.FMD.REC.1400.206

Health conditions studied

1

Description of health condition studied
Preterm Premature Rupture of Membrane
ICD-10 code
O42.91
ICD-10 code description
Preterm premature rupture of membranes, unspecified as to length of time between rupture and onset of labor

Primary outcomes

1

Description
Time Interval Between the beginning of Labour Induction and Occurrence of the Labour.
Timepoint
Time Interval Between the beginning of Labour Induction and Occurrence of the Labour.
Method of measurement
Timing

2

Description
Health of the newborn
Timepoint
Between minute one to minute five after the birth
Method of measurement
Apgar score

3

Description
Type of Labour
Timepoint
At the time of the birth
Method of measurement
Observation

Secondary outcomes

empty

Intervention groups

1

Description
Pregnant women diagnosed with Preterm Premature Rupture of the Membrane (PPROM) were administered Ingestible 25 micrograms of Misoprostol every 2 hours up to 12 doses.
Category
Treatment - Drugs

2

Description
Intervention group: Pregnant women diagnosed with Preterm Premature Rupture of the Membrane (PPROM) were administered Ingestible 50 micrograms of Misoprostol every 4 hours up to 6 doses.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Akbar Abadi Hospital
Full name of responsible person
The Nurse in Charge
Street address
Madar Street, Molavi Ave., Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1168743514
Phone
+98 21 5563 4949
Email
PR@iums.ac.ir
Web page address
https://en.iums.ac.ir/page.php?slct_pg_id=42169&sid=389&slc_lang=en

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Responsible Individual
Street address
Milad Tower International Conference Center Street, Hemmat Highway, Tehran, Iran
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Tehran
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1453514496
Phone
+98 21 86701
Email
info@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
Erfaneh Ebadi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
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Contact
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Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

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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

Undecided - It is not yet known if there will be a plan to make this available

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