

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Aug 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

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1168743514

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+98 21 5563 4949

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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

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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

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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Position

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Person responsible for updating data

Contact

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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