Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Comparison of Oral Misoprostol Tablets and Oxytocin for the Induction of Labor in Preterm Premature Rupture of Membranes

Protocol summary

Study aim

Comparison of the efficacy of oral Misoprostol and Oxytocin during induction in pregnant women with premature rupture of fetal membranes at 28 to 37 weeks gestation

Design

Initially, a preliminary cervical examination and a Bishop score and a history taking will be done. The lubricating gel will not be made during the preparation of the article. After definitive diagnosis of splenic rupture in speculum examination or positive fron test, patients are randomly using a random number table divided into two groups to induce labor.

Settings and conduct

Pregnant women will be NPOs at births and receive a CCR of 120 CC / h. The case group will be given 50 micrograms of misoprostol orally. In the control group, oral placebo and intravenous oxytocin in ringer serum will be started. In both groups, accurate and continuous monitoring of fetal heart rate and uterine contractions and progression of labor will be performed. , Pregnant will undergo cesarean section. Failure to respond to induction will result in cases where the Bishop score changes to less than five despite 6 hours of favorable contractions.

Participants/Inclusion and exclusion criteria

Pregnant mothers who have ruptured premature of membrane between 28 and 37 weeks of gestation

Intervention groups

In the intervention group 50mg misoprostol will be given orally every 4 hours up to a maximum of 6 doses. In the control group, oral placebo and intravenous oxytocin in ringer serum will be started at a dose of 2 mlu / min and 2 mlu / min every 10 minutes up to a maximum of 40 mlu / min.

Main outcome variables

Induction of labor

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191104045333N1**
Registration date: **2020-04-19, 1399/01/31**
Registration timing: **registered_while_recruiting**

Last update: **2020-04-19, 1399/01/31**
Update count: **0**

Registration date

2020-04-19, 1399/01/31

Registrant information

Name

Sepideh Besharati

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2222 0980

Email address

sepideh_besharati@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-20, 1398/12/01

Expected recruitment end date

2020-06-20, 1399/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Oral Misoprostol Tablets and Oxytocin for the Induction of Labor in Preterm Premature Rupture of Membranes

Public title
Preterm Labor and Mizoprostol
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
 Definite diagnosis of rupture of membrane on examination with speculum or positive frenne test Gestational age between 28 and 37 weeks One Pregnancy Cephalic presentation Bishop score ≤5
Exclusion criteria:
Fetal Heart Rate disorder Cesarean section history Placenta Previa Active cardiovascular disease, asthma, glaucoma
Age
From **18 years** old to **50 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **76**
Randomization (investigator's opinion)
Randomized
Randomization description
Individuals will be randomly divided into two groups using a random number table.
Blinding (investigator's opinion)
Single blinded
Blinding description
Participants will not be notified of the Mizoprostol or placebo.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shahid Beheshti University of Medical Sciences
Street address
Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
19839-63113
Approval date
2019-08-27, 1398/06/05
Ethics committee reference number
IR.SBMU.MSP.REC.1398.526

Health conditions studied

1

Description of health condition studied
Preterm Premature Rupture of Membranes
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Induction of labor until delivery
Timepoint
From induction to delivery
Method of measurement
Information will be recorded in terms of the time interval between the start of induction and delivery.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 50 µg oral misoprostol every 4 hours up to a maximum of 6 doses
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Mahdieh hospital
Full name of responsible person
Sepideh Besharati
Street address
Shoush Square - Fadaiyan Eslam St - Glass House Alley - Shahid Rajab Nia St
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mahdiyeh_hospital@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Tayebeh jahed
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Arabi Ave, Daneshjoo Blvd, Velenjak,
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tayebeh.jahed@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Spideh Besharati
Position
MD
Latest degree
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Gynecology and Obstetrics
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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
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
Undecided - It is not yet known if there will be 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