

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### Evaluation of mechanical and non-mechanical methods of cervix ripening in women with preterm rupture of membrane (PROM)

#### Protocol summary

##### Study aim

The purpose of this study is comparison to compare the Foley catheter and Misoprostol for cervical ripening of labor in women with premature rupture of membranes (PROM).

##### Design

Clinical trial with 2 intervention groups, with parallel, non-blind, randomized, phase 2 groups on 104 patients. Random number table was used for randomization

##### Settings and conduct

This study will be reviewed in Al-Zahra Hospital and Taleghani Hospital of Tabriz University of Medical Sciences in the period between 1399 and 1400. 104 pregnant women with ruptured membranes (PROM), were selected. Participants were randomly allocated to induction of labor by Foley catheter or oral misoprostol in a 1:1 ratio. This study is not blind. In the group treated with Foley catheter will use a Foley catheter size 16 with a 30 cc balloon and other group 25 micro grams of misoprostol tablet will be administered sublingually.

##### Participants/Inclusion and exclusion criteria

Pregnant women over 34 weeks gestational age with premature rupture of membranes, singleton pregnancy, and cephalic presentation will be included in the study, and if gestational age is below 34 weeks, Failure to prove premature rupture of the membranes will be excluded.

##### Intervention groups

Intervention group 1: will use a Foley catheter size 16 with a 30 cc balloon. the location of the catheter will be checked every 1 hour by pulling the catheter. If the Foley catheter does not come out automatically, we will remove the catheter within 8 hours after the catheter is placed. Intervention group 2: 25 micro grams of misoprostol tablet was administered sublingually every 4 hours up to maximum dose of 6 during cervical ripening.

##### Main outcome variables

The primary outcome in this study (interval from preparation to cervix) is in both methods. and the secondary outcome included: maternal and neonatal

complications, cesarean delivery incidence.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20121224011862N4**

Registration date: **2020-10-25, 1399/08/04**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-10-25, 1399/08/04**

Update count: **0**

##### Registration date

2020-10-25, 1399/08/04

##### Registrant information

##### Name

Farnaz Sahaf

##### Name of organization / entity

Women's Reproductive Health Research Center

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1553 9161

##### Email address

sahaf@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-09-25, 1399/07/04

##### Expected recruitment end date

2021-09-26, 1400/07/04

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of mechanical and non-mechanical methods of cervix ripening in women with preterm rupture of membrane (PROM)

**Public title**

Evaluation of mechanical and non-mechanical methods of cervix ripening in women with preterm rupture of membrane (PROM)

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Gestational age over 34 weeks with preterm rupture of membrane (PROM) Singleton pregnancy Absence of active labour Cephalic presentation Unfavorable cervix (bishop score of 6 or less)

**Exclusion criteria:**

Gestational age under 34 weeks Lack of proof of preterm rupture of membrane (PROM) bleeding Contraindications to natural childbirth Finding meconium in amniotic fluid at the beginning of the intervention Suspected of chorioamnionitis intrauterine growth restriction (IUGR) Having a history of cesarean section Breech presentation Multiple pregnancies

**Age**

No age limit

**Gender**

Female

**Phase**

2

**Groups that have been masked**

No information

**Sample size**

Target sample size: **104**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization in this study will be done one by one (1: 1) using a table of random numbers. 104 matte and sealed envelope samples will be prepared. Randomization will be performed by a non-research person and The type of intervention will be written by random allocation on paper and placed inside the envelopes. Envelopes will be numbered from number 1 to the end. The first person will be given the first envelope and this will continue until the last desired number; There will be 52 people in group 1 and 52 people in group 2, for a total of 104 people.

**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 Tabriz University of Medical Sciences

**Street address**

Third Floor, Central Building No.2, Golgasht St.

**City**

Tabriz

**Province**

East Azarbaijan

**Postal code**

5166616471

**Approval date**

2020-07-20, 1399/04/30

**Ethics committee reference number**

IR.TBZMED.REC.1399.393

**Health conditions studied****1****Description of health condition studied**

Premature rupture of membranes

**ICD-10 code**

O42.90

**ICD-10 code description**

Premature rupture of membranes, unspecified as to length of time between rupture and onset of labor, unspecified weeks of gestation

**Primary outcomes****1****Description**

Interval between induction commencement and obtaining bishop score of 6

**Timepoint**

During intervention

**Method of measurement**

In hour unit obtained by manual vaginal exam

**Secondary outcomes****1****Description**

delivery before 24 hours

**Timepoint**

up to 24 hours after intervention

**Method of measurement**

in hour unit obtained by questionnaire

## 2

### **Description**

neonatal complications

### **Timepoint**

up to 24 hours after birth

### **Method of measurement**

questionnaire and apgar score

## 3

### **Description**

oxytocin requirement

### **Timepoint**

during intervention

### **Method of measurement**

questionnaire

## 4

### **Description**

maternal complications

### **Timepoint**

24 hours after delivery

### **Method of measurement**

questionnaire

## 5

### **Description**

cesarean delivery incidence

### **Timepoint**

up to 48 hours after intervention

### **Method of measurement**

percentage unit obtained by questionnaire

## **Intervention groups**

### 1

#### **Description**

The group under catheter intervention will use a Foley catheter size 16 with a 30 cc balloon. It will be inserted into the lower segment of the uterus using a sterile And will be filled with 30 cc of distilled water or normal saline, the location of the catheter will be checked every 1 hour by pulling the catheter. If the Foley catheter does not come out automatically, we will remove the catheter within 8 hours after the catheter is placed.

#### **Category**

Treatment - Devices

### 2

#### **Description**

In the group under the intervention with misoprostol, misoprostol tablets with a dose of 25 micrograms will be used sublingually, If the cervix is not ripped, the prescribed dose will be repeated 6 hours later. Oxytocin will be used to induce or enhance uterine contractions after cervical rape and bishop scores greater than or equal to 6. In the absence of effective labor contractions.

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Alzahra Hospital

##### **Full name of responsible person**

Farnaz Sahaf

##### **Street address**

Alzahra Hospital, South Artesh St.

##### **City**

Tabriz

##### **Province**

East Azarbaijan

##### **Postal code**

5138665793

##### **Phone**

+98 41 3553 9161

##### **Email**

lahroudin@gmail.com

### 2

#### **Recruitment center**

##### **Name of recruitment center**

Taleghani Medical Research & Training Hospital

##### **Full name of responsible person**

Farnaz Sahaf

##### **Street address**

Taleghani Hospital, Rah Ahan St., Tabriz, Iran

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lahroudin@gmail.com

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Tabriz University of Medical Sciences

##### **Full name of responsible person**

Mohammad Samiei

##### **Street address**

Third Floor, Central Building of Number2, Golgasht Street

##### **City**

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##### **Province**

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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**

Tabriz 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**

Tabriz University of Medical Sciences

**Full name of responsible person**

Farnaz Sahaf

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Gynecology and Obstetrics

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

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**Position**

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Tabriz University of Medical Sciences

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Farnaz Sahaf

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**Latest degree**

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**Other areas of specialty/work**

Gynecology and Obstetrics

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**Postal code**

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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