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 comparisonto 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 group1: 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)

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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.
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Tabriz
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2

Recruitment center
Name of recruitment center
Taleghani Medical Research & Training Hospital
Full name of responsible person
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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
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5138665793

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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
Associte proffesor
Latest degree
Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
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Tabriz University Of Medical Sciences, Golgasht Street
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Person responsible for scientific inquiries

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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