Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Investigation of the effect of misoprostol alone in comparison with misoprostol with Foley catheter on cervical ripening for labor induction in women with preterm premature rupture of the membrane

Protocol summary

Study aim

Determination of the effect of misoprostol alone in comparison with misoprostol with Foley catheter on cervical ripening for labor induction in women with preterm premature rupture of the membranes

Design

This study is a randomized clinical trial conducted on 200 women with PPRM. Patients are randomly assigned to either misoprostol or misoprostol with a Foley catheter group based on the randomly generated list.

Settings and conduct

This study takes place in Ghaem and Omol-Banin hospitals without blinding. Therapeutic measures are carried out in both groups and finally, the interval between the onset of the intervention and delivery, in both groups are measured and compared. Patients are followed up through phone calls for 2 weeks in terms of incidence of febrile complications such as metritis, episiotomy and incision-site infection.

Participants/Inclusion and exclusion criteria

Inclusion criteria: alive singleton pregnancy, gestational age is greater than or equal to 36 weeks Exclusion criteria: symptoms of chorioamnionitis in mother or fetus at the onset of hospitalization, gestational Diabetes, fetal distress, previous cesarean section, active labor phase

Intervention groups

Control group: Immediately after admission, labor induction with 25 µg sublingual misoprostol is performed every 4 hours for patients. Intervention group: :Labor induction with 25 µg sublingual misoprostol is carried out every 4 hours with insertion of foley catheter size 18 and filling the balloon with 80 cc of normal saline, which is placed in dorsal lithotomy position in sterile conditions. Misoprostol is prescribed up to 4 doses in case of need.

Main outcome variables

The interval between the onset of induction and delivery; the delivery method; frequency of vaginal examinations; incidence of tachysystole; chorioamnionitis; the duration of administration of oxytocin and the infant's 1 and 5-minute apgar score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181123041731N1**
Registration date: **2019-01-27, 1397/11/07**
Registration timing: **registered_while_recruiting**

Last update: **2019-01-27, 1397/11/07**
Update count: **0**

Registration date

2019-01-27, 1397/11/07

Registrant information

Name

Malihe Rakhshani Far

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3801 2861

Email address

rakhshanifm951@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-08-01, 1396/05/10

Expected recruitment end date

2019-03-11, 1397/12/20

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigation of the effect of misoprostol alone in comparison with misoprostol with Foley catheter on cervical ripening for labor induction in women with preterm premature rupture of the membrane

Public title
Investigation of the effect of misoprostol in comparison with misoprostol with Foley catheter on cervical ripening for labor induction of in women with preterm premature rupture of the membrane
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Alive singleton pregnancy Gestational age is greater than or equal to 36 weeks Cephalic presentation Bishop Score is less than 4
Exclusion criteria:
Symptoms of chorioamnionitis in mother or fetus at the onset of hospitalization Gestational Diabetes Fetal distress Previous cesarean section and any contraindication for vaginal delivery Time of membrane rupture exceeds 12 hours Active labor phase
Age
No age limit
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **200**
Randomization (investigator's opinion)
Randomized
Randomization description
Random assignment is based on the random list generated by a computer. At first, two series with equal numbers of green and blue cards are prepared and placed into envelopes which are numbered according to the random list. Afterwards, the midwife assigns an envelope to each patient based on the numerical order.
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 Mashhad University of Medical Sciences
Street address
Central Building of Mashhad University of Medical Sciences (Ghorshi),Daneshgah 16, Daneshgah Street
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Approval date
2016-12-29, 1395/10/09
Ethics committee reference number
IR.MUMS.fm.REC.1395.490

Health conditions studied

1

Description of health condition studied
Preterm premature rupture of the membranes
ICD-10 code
O42
ICD-10 code description
Premature rupture of membranes

Primary outcomes

1

Description
time interval between the onset of induction and delivery
Timepoint
after intervention
Method of measurement
Patient's file

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Labor induction with 25 µg sublingual misoprostol is carried out every 4 hours for patients after hospitalization. Misoprostol is prescribed up to 4 doses in case of need.
Category
Treatment - Drugs

2

Description
Intervention group:Labor induction with 25 µg sublingual misoprostol is carried out every 4 hours with insertion of foley catheter size 18 and filling the balloon with 80 cc of normal saline, which is placed in dorsal lithotomy position in sterile conditions. In addition, light stretching is performed in order to examine the catheter exit.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Ommol-Banin hospital

Full name of responsible person
Masoumeh Mirteimouri

Street address
Ommol-Banin hospital, Azadi 16th, Azadi Avenue

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9144663595

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mirteimourim@mums.ac.ir

2

Recruitment center

Name of recruitment center
Ghaem hospital

Full name of responsible person
Malihe Rakhshani Far

Street address
Ghaem hospital, Ahmad Abad Ave

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Rakhshanifm951@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Dr Mohsen Tafaghodi

Street address
Central Building of Mashhad University of Medical Sciences (Ghorshi), Daneshgah 16, Daneshgah street

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ramresearch@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Malihe Rakhshani far

Position
resident

Latest degree
Medical doctor

Other areas of specialty/work
Gynecology and Obstetrics

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Ghaem hospital, Ahmad Abad Ave

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Person responsible for scientific

inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Masoumeh Mirteimouri

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

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Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Malihe Rakhshani Far

Position
resident

Latest degree
Medical doctor

Other areas of specialty/work
Gynecology and Obstetrics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is 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
Yes - There is 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
Not applicable

Title and more details about the data/document
All data can be shared after patients are made unidentifiable.

When the data will become available and for how long
Data can be accessible 6 months after results are published.

To whom data/document is available
Data will be available for researchers in universities and other scientific institutes.

Under which criteria data/document could be used
Carrying out analysis on data is permitted.

From where data/document is obtainable
Data can be accessible through sending an email to the corresponding author.

What processes are involved for a request to access data/document
After sending a request email to the corresponding author, data will be sent in 1 month.

Comments