Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Aug 2026

Comparison of the effects of oral and sublingual and buccal Misoprostol on induction of preterm premature rupture of membrane

Protocol summary

Study aim
Comparison of the effects of oral and sublingual and buccal Misoprostol on termination of pregnancy with preterm premature rupture of membrane

Design
clinical trial with intervention, control and parallel groups, randomized without blinding

Settings and conduct
This study is carried out without blinding on 120 women with preterm premature rupture of membrane admitted to Ommolbanin, Ghaem and Imam Reza Hospitals in Mashhad. Patients are assigned to 3 groups using simple randomization.

Participants/Inclusion and exclusion criteria
Inclusion criteria : women with single pregnancy; preterm premature rupture of membrane; gestational age of 37-42 weeks; cephalic presentation; informed consent of the individual to enter the study, low risk pregnancy (no complications such as preeclampsia and gestational diabetes and heart diseases); satisfactory fetal heart rate patterns; bishop score of less than 6; absence of contraindication to natural childbirth and no history of uterine scar Non-inclusion criteria : fetal macrosomia; symptoms of chorioamnionitis; use of other methods of initiating induction within the last 7 days; onset of uterine contractions

Intervention groups
Control group: prescribing 25 µg of sublingual Misoprostol every 4 hours up to a maximum of 6 doses
Intervention group 1: prescribing 50 µg of oral Misoprostol every 4 hours up to a maximum of 6 doses
Intervention group 2: prescribing 25 µg of buccal Misoprostol up to a maximum of 6 doses

Main outcome variables
the interval between induction and delivery

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190410043237N1**
Registration date: **2019-04-23, 1398/02/03**
Registration timing: **prospective**

Last update: **2019-04-23, 1398/02/03**
Update count: **0**

Registration date
2019-04-23, 1398/02/03

Registrant information
Name
Arezou Naderi Moghadam
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 51 3801 2477
Email address
nderima961@mums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-05-22, 1398/03/01

Expected recruitment end date
2021-05-22, 1400/03/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effects of oral and sublingual and buccal Misoprostol on induction of preterm premature rupture of membrane

Public title
The effect of oral and sublingual and buccal Misoprostol on induction of preterm premature rupture of membrane
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
women with single pregnancy preterm premature rupture of membrane gestational age of 37-42 weeks cephalic presentation informed consent of the individual to enter the study low risk pregnancy (no complications such as preeclampsia and gestational diabetes and heart diseases) satisfactory fetal heart rate patterns absence of contraindication to natural childbirth and no history of uterine scar bishop score of less than 6
Exclusion criteria:
onset of uterine contractions symptoms of chorioamnionitis fetal macrosomia use of other methods of initiating induction within the last 7 days
Age
No age limit
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
In envelope method, envelopes with random numbers are prepared and printed with the help of ''Randomize.com'' website. Envelopes are sealed and their contents are not visible from the outside. Firstly, the purpose of the study is explained to the individuals who meet the mentioned conditions. If willing, he/she signs the informed consent form and takes an envelope and opens it and based on its content, will enter either the intervention or control group.
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
2019-02-05, 1397/11/16
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1397.774

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
the interval between initiation of induction and delivery
Timepoint
after the intervention
Method of measurement
patient's file

Secondary outcomes

1

Description
natural delivery or cesarean section
Timepoint
after the intervention
Method of measurement
based on file

2

Description
investigation of Misoprostol side-effects
Timepoint
after medication use
Method of measurement
based on clinical observations

3

Description
investigation of maternal complications such as postpartum hemorrhage
Timepoint

after delivery

Method of measurement

based on clinical observations

4

Description

investigation of neonatal complications such as Apgar Score, dystocia, ICU hospitalization , Sepsis and bacteremia

Timepoint

Immediately after the birth of the infant

Method of measurement

based on clinical observations

Intervention groups

1

Description

Intervention group: prescribing 50 µg of oral Misoprostol (one fourth of 200-µg misoprostol poduced by SAMISAZ pharmaceutical company) every 4 hours up to a maximum of 6 doses

Category

Treatment - Drugs

2

Description

Intervention group2: prescribing 25 µg of buccal Misoprostol up to a maximum of 6 doses

Category

Treatment - Drugs

3

Description

Control group: prescribing 25 µg of sublingual Misoprostol every 4 hours

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ommol-Banin hospital

Full name of responsible person

Arezou Naderi Moghadam

Street address

Ommol-Banin hospital, Azadi 16th, Azadi Avenue

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9144663595

Phone

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Email

naderima961@mums.ac.ir

2

Recruitment center

Name of recruitment center

Ghaem hospital

Full name of responsible person

Atiyeh Mohamadzadeh Vatanchi

Street address

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9176699199

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3

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Arezou Naderi Moghadam

Street address

Imam Reza Hospital, Imam Reza Square, Ebn_e_Sina Avenue

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

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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
Arezou Naderi Moghadam
Position
resident
Latest degree
Medical doctor
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for scientific inquiries

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Assistant Professor
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Person responsible for updating data

Contact
Name of organization / entity
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Full name of responsible person
Atiyeh Mohamadzadeh Vatanchi
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Latest degree
Specialist
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
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
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