Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Clinical trial on the effectiveness of oxytocin and sublingual administration of misoprostol in premature rupture of membranes before the onset of the active phase of labor in term pregnancies

Protocol summary

Summary

Objective: To compare the effectiveness of oxytocin and sublingual misoprostol in premature rupture of membranes before the onset of the active phase of labor in term pregnancies. Design: A not blinded, block randomized clinical trial. Study population: Pregnant women at ≥ 37 weeks of gestation with premature rupture of membranes (before the onset of labor pain). Inclusion criteria: Premature rupture of membranes after 37 weeks of gestation; not being in the active phase of labor; Bishop score below six; cephalic presentation (vertex); singleton pregnancy; no evidence of clinical or laboratory signs confirming chorioamnionitis before the intervention; confirmation of the normal status of the fetal heart. Exclusion criteria: Prior history of uterine scar; placenta previa; unstable status of the fetal heart; non-cephalic presentation; sensitivity to misoprostol; history of glaucoma in misoprostol users; contraindication to vaginal delivery (e.g., narrow pelvis and genital herpes), and 8) parity ≥ 5. Sample size: 86 cases. Study intervention: The intervention group received 10 units of oxytocin in 1 L of ringer's lactate solution or normal saline before labor contractions. The control group was sublingually administered 25 µg of misoprostol per 4 h for a maximum of six doses. Study outcome: To compare the effectiveness of two drugs in intervals between drug administration and labor induction, labor induction and fetal delivery, and cervical dilation and fetal delivery (in minutes).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016042627615N1**
Registration date: **2016-06-01, 1395/03/12**
Registration timing: **prospective**
Last update:
Update count: **0**

Registration date

2016-06-01, 1395/03/12

Registrant information

Name

Elham Motamedimogadam

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3762 6485

Email address

motamedie912@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Mashhad University of Medical Sciences

Expected recruitment start date

2016-06-21, 1395/04/01

Expected recruitment end date

2018-01-21, 1396/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial on the effectiveness of oxytocin and sublingual administration of misoprostol in premature rupture of membranes before the onset of the active phase of labor in term pregnancies

Public title
Labor induction for premature rupture of membranes
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Premature rupture of membranes after 37 weeks of gestation; not being in the active phase of labor; Bishop score below six; cephalic presentation (vertex); singleton pregnancy; no evidence of clinical or laboratory signs confirming chorioamnionitis before the intervention; confirmation of the normal status of the fetal heart. Exclusion criteria: Prior history of uterine scar; placenta previa; unstable status of the fetal heart; non-cephalic presentation; sensitivity to misoprostol; history of glaucoma in misoprostol users; contraindication to vaginal delivery (e.g., narrow pelvis and genital herpes), and 8) parity ≥ 5.
Age
No age limit
Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **86**
Randomization (investigator's opinion)
Randomized
Randomization description
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
Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street
City
Mashhad
Postal code
Approval date
2014-04-08, 1393/01/19
Ethics committee reference number
IR. MUMS.REC.1393.181

Health conditions studied

1

Description of health condition studied
premature rupture of membranes at term
ICD-10 code
O60.1
ICD-10 code description
Preterm spontaneous labour with preterm delivery

Primary outcomes

1

Description
Intervals between drug administration and labor induction,
Timepoint
Measurements the time of delivery contractions create (at least 3 contractions 30 to 45 seconds in 10 minutes) after intervention.
Method of measurement
minutes

Secondary outcomes

1

Description
Interval between cervical dilatation and fetal delivery
Timepoint
After cervical dilatation
Method of measurement
minutes

Intervention groups

1

Description
Intervention group: To received 10 units of oxytocin in 1 L of ringer's lactate solution or normal saline before labor contractions.
Category
Treatment - Drugs

2

Description
Control group: To received 25 µg of misoprostol per 4 h for a maximum of six doses before labor contractions.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center

Emam Reza Hospital
Full name of responsible person
Elham Motamedi
Street address
Emam Reza Square, Ebne Sina Avenue
City
Mashhad

2

Recruitment center
Name of recruitment center
Ghaem Hospital
Full name of responsible person
Elham Motamedi
Street address
Ghaem Hospital, Ahmadabad Avenue
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
Street address
Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street
City
Mashhad
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for Research, Mashhad University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Elham Motamedi
Position
Gynecologist
Other areas of specialty/work
Street address
Emam Reza Hospital, Emam Reza Square, Ebne Sina Avenue
City
Mashhad
Postal code
Phone
+98 51 3762 6485
Fax
Email
elham_m2003@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Lela Pourali
Position
Assistant Professor
Other areas of specialty/work
Street address
Emam Reza Hospital, Emam Reza Square, Ebne Sina Avenue
City
Mashhad
Postal code
Phone
+98 51 3762 6485
Fax
Email
Pouralil2@mums.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Elham Motamedi
Position
Gynecologist
Other areas of specialty/work
Street address
Emam Reza Hospital, Emam Reza Square, Ebne Sina Avenue
City
Mashhad
Postal code
Phone
+98 51 3762 6485
Fax
Email
elham_m2003@yahoo.com

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty