

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 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

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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
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Emam Reza Square, Ebne Sina Avenue
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2

Recruitment center
Name of recruitment center
Ghaem Hospital
Full name of responsible person
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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
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Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street
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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
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

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Web page address	<i>empty</i>
Sharing plan	Informed Consent Form
	<i>empty</i>
Deidentified Individual Participant Data Set (IPD)	Clinical Study Report
<i>empty</i>	<i>empty</i>
Study Protocol	Analytic Code
<i>empty</i>	<i>empty</i>
Statistical Analysis Plan	Data Dictionary
	<i>empty</i>