

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Comparing misoprostol with oxytocin in induction of labor at term pregnancy with premature rupture of membranes

Protocol summary

Summary

Premature rupture of membranes (PROM) occurs in 8% of women at term. Prostaglandins such as misoprostol and oxytocin are used for induction of labor in PROM. In this study, 99 term pregnant women with PROM entered the study. Inclusion criteria: term pregnancy, demonstrated PROM <4 hours, single fetus pregnancy, parity1 and 2, cephalic presentation, labor pain were not started, normal cardiophitogram in fetus. Exclusion criteria: Previous uterine surgery, multiple pregnancy, abnormal presentations, fetal distress, weight of fetus>4kg, pregnancy>41 weeks, cord prolapse, labor pain, vaginal bleeding, diabetes, Asthma, chronic hypertension, preeclampsia, chorioamnionitis. Patients were randomized in two groups and they were matched using maternal age, parity and gestational age. First group was given 50 µgr of oral misoprostol every 4 hours for two doses and second groups was given two doses of placebo. Induction with oxytocin started after 12 hours of PROM if the delivery or effective contraction did not start. Solution of oxytocin was 10 IU in 1 lit serum (Ringer) that was started with 4mIU per/ min and added every 20 min up to 36 mIU per/min. The onset of labour pain and delivery, the mode of delivery, and maternal and fetal complications were the main outcome.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201105103820N3**

Registration date: **2011-06-06, 1390/03/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-06-06, 1390/03/16

Registrant information

Name

Zinatalsadat Bouzari

Name of organization / entity

Babol university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 1223 4651

Email address

z_b412003@yahoo.com

Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research and technology, Babol University of Medical sciences.

Expected recruitment start date

2008-12-21, 1387/10/01

Expected recruitment end date

2010-12-22, 1389/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing misoprostol with oxytocin in induction of labor at term pregnancy with premature rupture of membranes

Public title

Effect of misoprostol in iduction of labor

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: term pregnancy, demonstrated PROM <4 hours, single fetus pregnancy, parity1 and 2, cephalic presentation, labor pain were not started, normal

cardiophitogram in fetus. Exclusion criteria: Previous uterine surgery, multiple pregnancy, abnormal presentations, fetal distress, weight of fetus>4kg, pregnancy>41 weeks, cord prolapse, labor pain, vaginal bleeding, diabetes, Asthma, chronic hypertension, preeclampsia, chorioamnionitis.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Vice chancellor for Research and technology, Babol University of Medical Sciences

Street address

Ghanj Afroz Ave

City

Babol

Postal code

47176-41367

Approval date

2009-06-30, 1388/04/09

Ethics committee reference number

1782

Health conditions studied**1****Description of health condition studied**

Induction of labor

ICD-10 code

O80.8

ICD-10 code description

Other single spontaneous delivery

Primary outcomes**1****Description**

Induction of labor

Timepoint

2 hours, 8 hours, 12 hours

Method of measurement

Physical examination

Secondary outcomes**1****Description**

Duration of first stage duration of delivery

Timepoint

2 hours

Method of measurement

Physical examination

2**Description**

Duration of second stage of delivery

Timepoint

30 minutes

Method of measurement

Physical examination

3**Description**

Duration of delivery

Timepoint

hours

Method of measurement

time

Intervention groups**1****Description**

In first group: 50 µgr of oral misoprostol every 4 hours for two doses

Category

Treatment - Drugs

2**Description**

In second group: two doses of placebo and induction with oxytocin started after 12 hours of PROM if the delivery or effective contraction didn't start.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Aiatollah Rohani Hospital

Full name of responsible person

Dr Shahla Yazdani

Street address

Babol University of Medical sciences, Ghanj Afroz Ave

City

Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research and technology, Babol University of Medical sciences.

Full name of responsible person

Dr Ali Bijani

Street address

Babol University of Medical sciences, Ghanj Afroz Ave

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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 and technology, Babol 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**

Vice chancellor for Research and technology, Babol University of Medical Sciences

Full name of responsible person

Dr Shahla Yazdani

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Assistant Professor

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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