

# 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

**City**

Babol

**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

**Position**

Assistant Professor

**Other areas of specialty/work****Street address**

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### Person responsible for scientific inquiries

#### Contact

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### Person responsible for updating data

#### Contact

**Name of organization / entity**

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

**Full name of responsible person**

Zinatossadat Bouzari

**Position**

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*