Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Nov 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

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Zinatalsadat Bouzari
Name of organization / entity
Babol university of medical sciences
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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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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
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Position
Assisstant Professor

Other areas of specialty/work

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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