

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jun 2026

### Comparison of oral misoprostol and Intravenous oxytocin for induction of labor at Premature rupture of membrane in primigravida women

#### Protocol summary

##### Summary

The aim of this survey is comparison of oral Misoprostol versus intra venous oxytocin for cervical ripening in primiparous pregnant women with premature rupture of membrane. Those Primiparous pregnant women with premature rupture of membrane admitted in hospital between 36 to 42 weeks of pregnancy with inappropriate bishop score (less than 4). After written and informed consent to participate in the survey the women will be divided into two groups randomly, one group will be given 75 microgram of oral Misoprostol plus intra venous saline normal while another group intra venous oxytocin 2mlu/min increased 2 mlu/min any 10 minute plus oral placebo. Any person who involved as Executive agents in this study, have no information about prescribed drugs. Drug Doses will be repeated each 4 hour up to two times when it will be necessary. Fetal heart rate and uterus contractions will be checked before every dose prescription for about 10 minutes. Also vaginal examination will be done for every person before induction. In case of acquiring three contractions during ten minutes or reaching to active phase (at least 4cm dilatation) we won't give next dose. Finally we will compare these factors by using statistical methods: Time interval from labor induction beginning to active phase reaching, delivery type, vaginal delivery rate during first 12 hours, tachysystole and hyper stimulation, Apgar score, and 4 hours after induction bishop score, consumed dose of Misoprostol and maternal complication.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201104131946N9**

Registration date: **2011-08-21, 1390/05/30**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2011-08-21, 1390/05/30

##### Registrant information

###### Name

Mandana Mansur Ghanaie

###### Name of organization / entity

Guilan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 13 1322 5624

###### Email address

m\_m\_ghanaie@gums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for research, Guilan University of Medical Sciences

##### Expected recruitment start date

2011-09-23, 1390/07/01

##### Expected recruitment end date

2012-09-22, 1391/07/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of oral misoprostol and Intravenous oxytocin for induction of labor at Premature rupture of membrane in primigravida women

##### Public title

Comparison of oral misoprostol and Intravenous oxytocin for induction of labor at Premature rupture of membrane

in primigravida women

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: a) single pregnancy (between 36 to 42 weeks); b) vertex presentation; c) bishop score equal or less than four; d) absence of uterus spontaneous contractions; e) normal fetal heart rate; f) cephalopelvic proportion. Exclusion criteria: a) sensitivity to PGs; b) previous history of cesarean; c) uterus wall scar; d) preeclampsia or blood pressure more than 140/90 mmHg; e) history of heart disease, asthma, glaucoma; f) IUGR; g) age under 18 years

**Age**

From **18 years** old to **45 years** old

**Gender**

Male

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **240**

**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**

Ethics committee Guilan University of Medical Sciences

**Street address**

Vice Chancellor for research, Guilan University of Medical Sciences, Melat st, Namjoo Ave

**City**

Rasht

**Postal code**

0098

**Approval date**

2011-07-20, 1390/04/29

**Ethics committee reference number**

1900189604

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

Pregnancy, childbirth and the puerperium

**ICD-10 code**

O74.8

**ICD-10 code description**

Other complications of anaesthesia during labour and delivery

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

Comparison of oral misoprostol and Intravenous oxytocin

**Timepoint**

Every four hours up to two times

**Method of measurement**

Vaginal examination and record in Questionnaire

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

Determination of time interval from labor induction beginning to active phase reaching

**Timepoint**

Time recording of induction beginning and delivery

**Method of measurement**

Time recording of induction beginning and delivery in Questionnaire

**2****Description**

Delivery type frequency

**Timepoint**

After delivery

**Method of measurement**

Patients' medical document

**3****Description**

Vaginal delivery frequency during first 12 hours

**Timepoint**

After delivery

**Method of measurement**

Patients' medical document

**4****Description**

Tachysystole incidence

**Timepoint**

Time recording of induction beginning up to active phase

**Method of measurement**

Patients' medical document

## 5

### **Description**

Hyper stimulation incidence

### **Timepoint**

Time recording of induction beginning up to active phase

### **Method of measurement**

Patients' medical document

## 6

### **Description**

Fetal Heart Rate disorder

### **Timepoint**

Time recording of induction beginning and delivery

### **Method of measurement**

Patients' medical document

## 7

### **Description**

Failure to progress frequency

### **Timepoint**

Entering to active phase up to delivery

### **Method of measurement**

Patients' medical document

## 8

### **Description**

Determination of Bishop Score alteration average after 4 hours

### **Timepoint**

After 4 hours from induction beginning

### **Method of measurement**

Vaginal examination

## 9

### **Description**

Determination of NICU admission rate

### **Timepoint**

After delivery

### **Method of measurement**

Patients' medical document

## 10

### **Description**

APGAR score less than 7

### **Timepoint**

After delivery

### **Method of measurement**

Patients' medical document

## 11

### **Description**

Frequency of maternal complication

### **Timepoint**

Time recording of induction beginning and delivery

### **Method of measurement**

Patients' medical document

## **Intervention groups**

### 1

#### **Description**

Prescription of 75 microgram of oral Misoprostol plus intra venous normal saline

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Prescription of intra venous oxytocin 2mlu/min increased 2 mlu/min any 10 minute.

#### **Category**

Treatment - Drugs

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Guilan University of Medical Sciences. Alzahra Hospital

##### **Full name of responsible person**

Dr. Mandana Mansur Ghanaie

##### **Street address**

##### **City**

Rasht

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Vice chancellor for researchr, Guilan University of Medical Sciences

##### **Full name of responsible person**

Dr. Abdolrasol Sobhani

##### **Street address**

Namjo street, Mellat street

##### **City**

Rasht

#### **Grant name**

#### **Grant code / Reference number**

#### **Is the source of funding the same sponsor organization/entity?**

Yes

#### **Title of funding source**

Vice chancellor for researchr, Guilan 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**  
Guilan University of Medical Sciences  
**Full name of responsible person**  
Dr. Mandana Mansur Ghanaie

**Position**  
Accosiated professor of Obstetrics and Gynecology,

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## Person responsible for updating data

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Seyedeh Maryam Mousavi Chahardeh

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
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**Full name of responsible person**  
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Associated professor of Obstetrics and Gynecology

**Other areas of specialty/work**

**Street address**  
Reproductive Health Research center, Department of  
Ob & Gyn, Alzahra Hospital, Guilan University of

## 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*