

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### A comparison of vaginal misoprostol tablet and oxytocin in induction of labor at term pregnancy

#### Protocol summary

##### Summary

**Abstract:** Objectives: Recently elective inductions of labor at term have increased dramatically which may be in part due to patient and clinicians desire to arrange a convenient time of delivery. Termination of pregnancy before emerging labor pain is an important concern. Because induction of labor is one of the most commonly performed obstetrical procedures clinicians all over the world investigate to find a safe technique for mother and neonate. Labor induction with PGE1 is one of the selections. Our objective was to compare vaginal delivery, maternal, fetal and neonatal complication between induction of labor with oxytocin and misoprostol. Methods: we selected one hundred - two cases with term pregnancy , not in active labor, singleton pregnancy, vertex presentation, normal fetal heart rate reactivity and Bishop score<6, consented to participate in the study. Fifty-one of the cases were included in misoprostol group and a 100 µg misoprostol tablet was placed in the posterior vaginal fornix. Another 51 cases were included in oxytocin group. Labor characteristics, maternal and neonatal outcome were analyzed.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201202018897N1**

Registration date: **2012-03-07, 1390/12/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2012-03-07, 1390/12/17

##### Registrant information

**Name**

Safoura Rouholamin

##### Name of organization / entity

Isfahan University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 1236 7001

##### Email address

s\_rouholamin@med.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Isfahan University of Medical Sciences

##### Expected recruitment start date

2008-12-21, 1387/10/01

##### Expected recruitment end date

2009-08-21, 1388/05/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

A comparison of vaginal misoprostol tablet and oxytocin in induction of labor at term pregnancy

##### Public title

Effect of misoprostol on labor

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria: singleton live pregnancy at term(GA $\geq$  37week) in the cephalic presentation; absent of active labor; unfavorable cervix(Bishop scor $\leq$ 6) and normal fetal heart rate tracing. Exclusion criteria: known cephalopelvic disproportion; abnormal presentation; previous cesarean delivery or other type of uterine surgery; cervical cancer; fetal macrosomia; active herpes

genitalia; multiparity and fetal anomaly.

#### Age

From **18 years** old to **35 years** old

#### Gender

Female

#### Phase

N/A

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **102**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Single

#### Other design features

### Secondary Ids

empty

### Ethics committees

#### 1

##### Ethics committee

###### Name of ethics committee

Vice chancellor-Isfahan university of medical science

###### Street address

Pol felezi,motahari st. shahid beheshti hospital

###### City

Isfahan

###### Postal code

8184851153

##### Approval date

2008-11-05, 1387/08/15

##### Ethics committee reference number

387303

### Health conditions studied

#### 1

##### Description of health condition studied

Efficacy on induction of labor

##### ICD-10 code

O61.0

##### ICD-10 code description

Failed medical induction of labour

### Primary outcomes

#### 1

##### Description

Interval from induction to true labor

##### Timepoint

Vaginal exam for evaluation of dilatation and effacement

##### Method of measurement

By vaginal exam

#### 2

##### Description

Interval from true labor to delivery

##### Timepoint

Vaginal exam for evaluation of dilatation and effacement  
q 1 hour

##### Method of measurement

By vaginal exam

#### 3

##### Description

Interval from induction to delivery

##### Timepoint

Vaginal exam for evaluation of dilatation and effacement  
q 1 hour

##### Method of measurement

By vaginal exam

### Secondary outcomes

#### 1

##### Description

Rate of vaginal delivery

##### Timepoint

At delivery time and 48 hours afterthat

##### Method of measurement

By clinical evaluation and add to form

#### 2

##### Description

Post partum complication

##### Timepoint

At delivery time and 48 hours afterthat

##### Method of measurement

By clinical evaluation and add to form

#### 3

##### Description

Neonatal outcom

##### Timepoint

At delivery time and 48 hours afterthat

##### Method of measurement

By clinical evaluation and add to form

### Intervention groups

#### 1

##### Description

Insertion of 100 microgram vaginal misoprostol

##### Category

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Shahid beheshti hospital

**Full name of responsible person**

**Street address**

**City**

Isfahan

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Faculty of Medicine

**Full name of responsible person**

Vice chancellor for research, Isfahan university of  
medical science

**Street address**

Isfahan medical university, hezarjreeb street

**City**

Isfahan

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Faculty of Medicine

**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**

Faculty of medicine

**Full name of responsible person**

Dr.Rouholamin safoura

**Position**

Assistant professor

### Other areas of specialty/work

**Street address**

Beheshti hospital, pol felezi

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s\_rouholamin@med.mui.ac.ir

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Faculty of medicine (Isfahan medical university)

**Full name of responsible person**

Dr. zahra allameh

**Position**

Associate professor

**Other areas of specialty/work**

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+91 33159672

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**Web page address**

## Person responsible for updating data

### Contact

## 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*