

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### Comparing the Effect of Oral Misoprostol and Intravenous Oxytocin on Labor Induction in pregnant women

#### Protocol summary

##### Study aim

Comparing the Effect of Oral Misoprostol and Intravenous Oxytocin on Labor Induction

##### Design

A randomized, double blind, parallel clinical trial including 130 patients with postdate pregnancy receiving two intervention for induction of labor. The patients, intervention applicators and outcome assessors will be blinded toward the study groups.

##### Settings and conduct

A university hospital affiliated with Fasa University of Medical Sciences. The drugs would be prepared in pharmacology department in dark syringes and uniform tablets and would be provided to the physician and caring nurse blindly. Those recording the outcome will also be blinded toward the study groups.

##### Participants/Inclusion and exclusion criteria

We included women over 18 years old, singleton pregnancy, cervical closure (Bishop score greater than six), first and second pregnancy. We excluded those with multiple pregnancy, emergency cesarean section and maternal sensitivity to oxytocin, misoprostol and prostaglandin analogues.

##### Intervention groups

Patients in case group will receive 10 units of intravenous oxytocin for labor induction. Patients in control group will receive 50 mg oral Misoprostol every 4 hours for 2 days maximally.

##### Main outcome variables

Successful delivery within 48 hours after intervention  
Route of delivery (Cesarean delivery vs Natural Vaginal delivery)  
Frequency of uterine contractions per hour  
Drug adverse effects Apgar at 1- and 5-min

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20171111037374N1**

Registration date: **2018-07-03, 1397/04/12**

Registration timing: **retrospective**

Last update: **2018-07-03, 1397/04/12**

Update count: **0**

##### Registration date

2018-07-03, 1397/04/12

##### Registrant information

###### Name

Hadi Zare Marzouni

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 911 861 2103

###### Email address

zaremh931@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-12-22, 1396/10/01

##### Expected recruitment end date

2018-03-26, 1397/01/06

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparing the Effect of Oral Misoprostol and Intravenous Oxytocin on Labor Induction in pregnant women

##### Public title

Comparing the Effect of Oral Misoprostol and Intravenous

Oxytocin on Labor Induction

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Gestational age more than 42 weeks first and second pregnancy women over 18 years old singleton pregnancy, cervical closure (Bishop score greater than six)

### Exclusion criteria:

Multiple pregnancies need for immediate cesarean section history of uterine scarring placenta previa vaginal bleeding more than normal postpartum bleeding heart, liver and kidney diseases history of sensitivity to Oxytocin, Misoprostol or prostaglandin analogues severe congenital anomalies in the fetus.

## Age

From **18 years** old

## Gender

Female

## Phase

2-3

## Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

## Sample size

Target sample size: **140**

## Randomization (investigator's opinion)

Randomized

## Randomization description

The included patients were randomly assigned to 2 study groups using a computer-based random digit generator utilizing the admission numbers

## Blinding (investigator's opinion)

Single blinded

## Blinding description

Participants are unaware of being present in the case and control group. Also outcome assessor and data analyser will be blind

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Fasa University of Medical Sciences

##### Street address

Ebne Sina Square

## City

Fasa

## Province

Fars

## Postal code

7461686688

## Approval date

2017-09-05, 1396/06/14

## Ethics committee reference number

IR.FUMS.REC.1396.222

## Health conditions studied

### 1

#### Description of health condition studied

Abdominal pregnancy

#### ICD-10 code

O00.0

#### ICD-10 code description

Abdominal pregnancy

### 2

#### Description of health condition studied

(Induced) termination of pregnancy with other and unspecified complications

#### ICD-10 code

O04.8

#### ICD-10 code description

(Induced) termination of pregnancy with other and unspecified complications

## Primary outcomes

### 1

#### Description

Delivery withing 48 hours after intervention

#### Timepoint

48 hours after intervention

#### Method of measurement

Recording the number of patients with successful delivery within 48 hours

### 2

#### Description

Route of delivery

#### Timepoint

At time if delivery

#### Method of measurement

Recording the route of delivery (Cesarean or vaginal delivery)

### 3

#### Description

Neonatal Apgar

#### Timepoint

1 and 5 minutes after birth

#### Method of measurement

Apgar

## Secondary outcomes

1

### Description

Adverse Effects

### Timepoint

1, 2, 4, 8 and 10 days after intervention

### Method of measurement

Adverse drug effects form

## Intervention groups

1

### Description

Intervention group: 50 micrograms of oral misoprostol for induction of labor. If no appropriate uterine contractions were observed, patients received 50 mg Misoprostol every four hours and finally twice a day. Intravenous placebo was also received in the case group.

### Category

Treatment - Drugs

2

### Description

Control group: 10 units of Oxytocin dissolved in 1000 cc of dextrose 5% for labor induction. This group also received oral placebo tablets at the same time.

### Category

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Educational hospital of Fasa University of Medical Science, Fasa, Iran

#### Full name of responsible person

Roya Kokabi

#### Street address

Fasa University of Medical Science, Fasa, Iran

#### City

Fasa

#### Province

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#### Postal code

74616 86688

#### Phone

+98 71 5335 0994

#### Email

roya.kokabi11111@gmail.com

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Fasa University of Medical Sciences

#### Full name of responsible person

Mojtaba Farjam

#### Street address

Ebne Sina square, Fasa, Iran

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farjam@fums.ac.ir

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Fasa University of Medical Sciences

### Proportion provided by this source

100

### Public or private sector

Public

### Domestic or foreign origin

Domestic

### Category of foreign source of funding

*empty*

### Country of origin

### Type of organization providing the funding

Academic

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Fasa University of Medical Sciences

#### Full name of responsible person

Roya Kokabi

#### Position

Assistant professor

#### Latest degree

Specialist

#### Other areas of specialty/work

Gynecology and Obstetrics

#### Street address

Ebne Sina square, Fasa

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Fasa University of Medical Sciences

**Full name of responsible person**

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**Position**

Assistant professor

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Fasa University of Medical Sciences

**Full name of responsible person**

Roya Kokabi

**Position**

Assistant professor

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available

**Title and more details about the data/document**

After the end of the project and the collection of information, the results are published as an article.

**When the data will become available and for how long**

The results will available 6 months after the publication

**To whom data/document is available**

The findings will be available to the public, researchers and clinicians.

**Under which criteria data/document could be used**

All data on which non-personally identifiable data is sampled are available.

**From where data/document is obtainable**

Applicants can receive information from the article. In addition, they can answer their questions from Corresponding Author by e-mail.

**What processes are involved for a request to access data/document**

Applicants can receive information from the article. In addition, they can answer their questions from Corresponding Author by e-mail.

**Comments**