

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

25 Jun 2026

### A comparison between the effects of oral titrated suspension of misoprostol and infusion of oxytocin for labor induction in term pregnancies.

#### Protocol summary

##### Summary

Objectives: Comparison between the effects of oral titrated suspension of misoprostol and infusion of oxytocin for labor induction in term pregnancies. Design: Randomized clinical trial. Setting and conduct: In misoprostol group, mioprostol (synthetic prostaglandin E1 analogue) suspension (Cytotec, 200 micro-gram tablet will be solved in 200 cc of distilled water), will be administered in 20 micro-gram dosages; (20 milliliter) every 2 hours for 3 doses (total of 60 µg). Uterine contractions will be monitored during this period. If contractions are appropriate (=>3 forceful contractions with a duration of 40 seconds in 10 minutes), drug administration will be terminated. In case of inappropriate contractions, and reassuring FHR, misoprostol will be increased up to 40 µg every 2 hours until having appropriate contractions and then, administration of misoprostole will be terminated. In this group, serum with distilled water will be used for blinding the study similar to the oytocin group. In oxytocin group, intravenous oxytocin will be infused in a dosage of 2.5 mIU per minute and will be doubled every 15 minutes until having appropriate contractions. Maximum dosage of oxytocin is 60 mIU per minute. In this group, water will be used for blinding the study similar to the misoprostole group. Participants: Inclusion criteria includes: maternal age between 20-40 years; certain gestational age between 40-42 weeks; singleton with cephalic presentation; Bishop Score of more than 5 and favorable pelvis in vaginal examination. Exclusion criteria includes: parity of more than 3; high risk pregnancy; using prostaglandins during present pregnancy and spontaneous labor. Interventions: administration of oral titrated solution of misoprostol and infusion of oxytocin. Main outcome: Number of deliveries during the first 24 hours.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201602102624N19**  
Registration date: **2016-04-05, 1395/01/17**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-04-05, 1395/01/17

##### Registrant information

##### Name

Maryam Kashanian

##### Name of organization / entity

Iran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 7752 3487

##### Email address

maryamka@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Investigator.

##### Expected recruitment start date

2015-12-22, 1394/10/01

##### Expected recruitment end date

2016-12-21, 1395/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

A comparison between the effects of oral titrated suspension of misoprostol and infusion of oxytocin for labor induction in term pregnancies.

### Public title

Labor induction with oxytocin and misoprostol.

### Purpose

Treatment

### Inclusion/Exclusion criteria

Inclusion criteria includes: maternal age between 20-40 years; certain gestational age between 40-42 weeks; singleton with cephalic presentation; Bishop Score of more than 5 and favorable pelvis in vaginal examination. Exclusion criteria includes: parity of more than 3; blood pressure of equal or/and more than 160/110, non reassuring NST or any evidence of fetal distress; proteinuria of more than 2 grams; suspicion to HELLP syndrome; poly-hydramnios; probable macrosomia; any vaginal bleeding more than bloody show; history of any surgical operation on the uterus; using prostaglandins during present pregnancy and spontaneous labor.

### Age

From **20 years** old to **40 years** old

### Gender

Female

### Phase

2-3

### Groups that have been masked

*No information*

### Sample size

Target sample size: **80**

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Double blinded

### Blinding description

### Placebo

Used

### Assignment

Parallel

### Other design features

Randomization was performed as stratified block randomization.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethic committee of Iran University of Medical Sciences

##### Street address

Hemmat highway, Chamran Cross

##### City

Tehran

##### Postal code

##### Approval date

2014-07-28, 1393/05/06

##### Ethics committee reference number

93/2129 /105/3

## Health conditions studied

### 1

#### Description of health condition studied

Labor and delivery

#### ICD-10 code

080

#### ICD-10 code description

Delivery

### 2

#### Description of health condition studied

Labor and delivery

#### ICD-10 code

080.0

#### ICD-10 code description

Spontaneous vertex delivery

### 3

#### Description of health condition studied

Labor and delivery

#### ICD-10 code

080.9

#### ICD-10 code description

Single spontaneous delivery, unspecified

### 4

#### Description of health condition studied

Labor and delivery

#### ICD-10 code

082

#### ICD-10 code description

Single delivery by caesarean section

### 5

#### Description of health condition studied

Labor and delivery

#### ICD-10 code

082.1

#### ICD-10 code description

Delivery by emergency caesarean section

## Primary outcomes

### 1

#### Description

Delivery during first 24 hours of induction of labor

#### Timepoint

24 hours

## Method of measurement

Questionnaire

## Secondary outcomes

### 1

#### Description

Number of deliveries during 6-12-18 hours from the beginning of induction

#### Timepoint

6-12-18 hours from the beginning of induction

#### Method of measurement

Questionnaire

### 2

#### Description

Duration of stage 1 , 2 and 3 of labor.

#### Timepoint

After birth

#### Method of measurement

Questionnaire

### 3

#### Description

Interval between the beginning of induction up to the beginning of suitable contractions( 3 forceful contractions during 10 minutes).

#### Timepoint

Beginning of suitable contractions

#### Method of measurement

Questionnaire

### 4

#### Description

Uterine tachysystole

#### Timepoint

During labor

#### Method of measurement

Questionnaire

### 5

#### Description

Number of vaginal deliveries and instrumental and cesarean deliveries

#### Timepoint

After birth

#### Method of measurement

Data sheets

### 6

#### Description

Indications for cesarean deliveries.

#### Timepoint

After birth

#### Method of measurement

Data sheets

### 7

#### Description

Fetal distress

#### Timepoint

During labor and fetal monitoring

#### Method of measurement

Questionnaire

### 8

#### Description

Neonatal Apgar Score

#### Timepoint

After birth

#### Method of measurement

Data sheets

### 9

#### Description

NICU admission

#### Timepoint

After birth up to discharge.

#### Method of measurement

data sheets

### 10

#### Description

Duration of hospital stay for mother and baby

#### Timepoint

After birth up to discharge.

#### Method of measurement

Data sheets

## Intervention groups

### 1

#### Description

Intervention group: Administration of oral misoprostol

#### Category

Treatment - Drugs

### 2

#### Description

Infusion of oxytocin

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Akbarabadi Teaching Hospital

##### Full name of responsible person

Maryam Kashanian

##### Street address

Molavi avenue, Molavi Cross.

**City**  
Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Vice chancellor for research ,Iran University of Medical Sciences.

**Full name of responsible person**  
Dr Seyed Ali Javad Mousavi

**Street address**  
Hemmat High way, Chamran Cross.

**City**  
Tehran

#### 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 ,Iran 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**  
Iran University of Medical Sciences

**Full name of responsible person**  
Maryam Kashanian

**Position**  
Professor.

#### Other areas of specialty/work

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## Person responsible for scientific

## inquiries

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Professor

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#### Web page address

## 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*