

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

26 Jun 2026

### A comparative study of vaginal misoprostol and intravenous oxytocin for induction of labor in women with second trimester pregnancy

#### Protocol summary

2013-09-20, 1392/06/29

##### Summary

Second trimester labor induction is a major problem in obstetrics. To compare the effectiveness of vaginal misoprostol and intravenous oxytocin in induction of labor, 100 women 12-24 weeks of gestation will participate in a randomised controlled way. The inclusion criteria consist of mothers with Intra uterine fetal death; fetal anomaly; Premature rupture of membrane; maternal complications and parity below 6. Mothers with multigestations; chorioamnionitis; prostaglandin contraindication and sufficient uterine contraction will be excluded from the study. One of two groups will get 200 micro gram vaginal tablet misoprostol and repeat after 12 hours if necessary. Another group of patients will receive 50 units of oxytocin in 500 ml of dextrose- saline infusion over 3 hours, one hour of no oxytocin, followed by a 100 unit in 500 ml solution over 3 hours, another of rest, and a 150 units in 500 ml over 3 hours, the oxytocin will be increased to a final concentration of 300 units in 500 ml. In either treatment arm the assigned medication will be continued until either maximum dose will be administered or delivery will occur, whichever comes first. The two groups will be compared for induction to delivery intervals and their safety during inductions. The success rate in misoprostol group and in second group (after 24 hours) will be assessed and compared.

##### Registrant information

###### Name

Golnaz Rezaeizadeh

###### Name of organization / entity

Maternal Fetal Neonatal Research Center, Tehran University of Medical Sciences, Tehran, Iran

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 6119 2357

###### Email address

mfnhrc@tums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Hormozgan University Medical of Sciences

##### Expected recruitment start date

2013-09-23, 1392/07/01

##### Expected recruitment end date

2014-01-21, 1392/11/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

A comparative study of vaginal misoprostol and intravenous oxytocin for induction of labor in women with second trimester pregnancy

##### Public title

Comparison of 2 different methods in Second trimester labor induction

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201307159568N5**

Registration date: **2013-09-20, 1392/06/29**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

inclusion criteria: Intra uterine fetal death; fetal anomaly; PROM; maternal indications; Parity<5; previous cesarean section, Exclusion criteria: multi pregnancy; prostaglandin contraindication; uterine contraction; mothers dissatisfaction; more than 2 cesarean sections; chorioamnionitis; placenta previa

#### Age

From **20 years** old to **35 years** old

#### 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)

Single blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Bandar Abas University of Medical Sciences

##### Street address

Bandar Aabas, Medical University

##### City

Bandar Abas

##### Postal code

#### Approval date

2004-09-22, 1383/07/01

#### Ethics committee reference number

83/84/32

## Health conditions studied

### 1

#### Description of health condition studied

pregnancy

#### ICD-10 code

O00-O08

#### ICD-10 code description

Pregnancy with abortive outcome

## Primary outcomes

### 1

#### Description

induction- to-delivery interval time

#### Timepoint

24 hours after misoprostol and oxytocin administration

#### Method of measurement

clock

## Secondary outcomes

### 1

#### Description

Induction complications

#### Timepoint

During induction procedurs

#### Method of measurement

Observation and phisical exam

## Intervention groups

### 1

#### Description

comparison of induction of labor in misoprostol & oxytocin groups. one of two groups will get 200 micro gram vaginal tablet misoprostol and repeat after 12 hours if necessary.

#### Category

Treatment - Drugs

### 2

#### Description

Another group of patients will receive 50 units of oxytocin in 500 ml of dextrose- saline infusion over 3 hours, one hour of no oxytocin, followed by a 100 unit in 500 ml solution over 3 hours, another of rest , and a 150 units in 500 ml over 3 hours , the oxytocin will increased to a final concentration of 300 units in 500 ml.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shariaty Hospital. Bandar Abas

##### Full name of responsible person

Dr. Zhila Abedi Asl

##### Street address

##### City

Bandar Abas

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Hormozgan University of Medical Sciences

**Full name of responsible person**

Dr. Abedi

**Street address**

Hormozgan-Bandar Abas . University of Medical Sciences

**City**

Bandar Abas

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Hormozgan 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**

Maternal, fetal and neonatal research center, tehran Medical University

**Full name of responsible person**

Zahra Farahani

**Position**

Researcher

**Other areas of specialty/work****Street address**

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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

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**Full name of responsible person**

Dr. Zhila Abedi Asl

**Position**

Obstetrician & Gynecologist

**Other areas of specialty/work****Street address**

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## Person responsible for updating data

#### Contact

**Name of organization / entity**

Maternal, Fetal & nNeonatal Research Center of Tehran Medical University

**Full name of responsible person**

Zahra Farahani

**Position**

Researcher, Physiologist

**Other areas of specialty/work****Street address**

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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*