

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

06 Jul 2026

### Comparison of the effect of misoprostol alone and misoprostol together with vaginal estrogen in preparing the cervix and induction of labor in term pregnancies

#### Protocol summary

##### Study aim

Comparison of the effect of misoprostol alone and misoprostol together with vaginal estrogen in preparing the cervix and induction of labor in term pregnancies

##### Design

This three-phase clinical trial, with parallel groups, randomized (using the allocation randomization rule) is performed on 200 pregnant women.

##### Settings and conduct

In this interventional study, 200 pregnant women are selected by convenience sampling method in Yas Hospital. This study is double-blind, the participants and the physician who evaluates the outcome are kept blind.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria include term pregnancy (Gestational age >37 weeks), nulliparous woman, singleton pregnancy, and alive Fetus with the cephalic presentation, and Bishop score < 5. Exclusion criteria: Misoprostol or estrogen contraindication, women with a history the uterus surgery, and a history or family history of thromboembolism.

##### Intervention groups

In both groups, For termination of pregnancy, 25 micrograms of misoprostol is placed sublingual. According to the uterine contractions, every 3 to 6 hours, 25 micrograms of misoprostol is prescribed up to 4 times, or until the active phase of labor begins, or until the bishop score is 8 or higher, or until the rupture of membrane. In the intervention group, in the first and second times of misoprostol administration, an applicator of Stromarin (estrogen) cream is also placed in the posterior part of the vagina.

##### Main outcome variables

The interval from induction with misoprostol to the attainment of 6 cm cervical dilation, from 6 cm cervical dilation to full cervical dilation, and from full cervical dilation to active phase of labor.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230611058454N1**

Registration date: **2023-06-24, 1402/04/03**

Registration timing: **prospective**

Last update: **2023-07-25, 1402/05/03**

Update count: **1**

##### Registration date

2023-06-24, 1402/04/03

##### Registrant information

##### Name

Fatemeh Golshahi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4216 0852

##### Email address

fgolshahi@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-07-23, 1402/05/01

##### Expected recruitment end date

2024-08-21, 1403/05/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

## Scientific title

Comparison of the effect of misoprostol alone and misoprostol together with vaginal estrogen in preparing the cervix and induction of labor in term pregnancies

## Public title

The effect of misoprostol alone and misoprostol together with vaginal estrogen in induction of labor

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Term pregnancy (Gestational age >37 weeks)  
Nulliparous woman Singleton pregnancy Alive Fetus with cephalic presentation Bishop score < 5

### Exclusion criteria:

Misoprostol or estrogen contraindication Women with a history the uterus surgery Women with a history or family history of thromboembolism

## Age

No age limit

## Gender

Female

## Phase

3

## Groups that have been masked

- Participant
- Outcome assessor

## Sample size

Target sample size: **200**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Random allocation rule: First, 100 letters A and 100 letters B are written on special papers that are not marked inside. Then all of them are placed in a bag and for each patient, after obtaining informed consent, a paper is removed randomly and without replacement, and based on the letter written on it, the desired intervention is performed for the patient. In addition, interventions A (misoprostol) or B (misoprotol and estrogen) are determined by a lot.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

This study is performed double-blind, the physician evaluating outcomes and the participants do not know the type of treatment.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

## 1

### Ethics committee

#### Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

#### Street address

Ethics committee of Tehran University of Medical Sciences, School of Medicine, Pour Sina St., Qods Ave.

#### City

Tehran

#### Province

Tehran

#### Postal code

1598718311

### Approval date

2023-06-11, 1402/03/21

### Ethics committee reference number

اخلاق: IR.TUMS.MEDICINE.REC.1402.171

## Health conditions studied

## 1

### Description of health condition studied

Labor induction

### ICD-10 code

O61.0

### ICD-10 code description

Failed medical induction of labor

## Primary outcomes

## 1

### Description

Interval from induction with misoprostol to the attainment of 6 cm cervical dilation

### Timepoint

Once, after delivery

### Method of measurement

Information entered in the patient's delivery record

## 2

### Description

Interval from 6 cm cervical dilation to full cervical dilation

### Timepoint

Once, after delivery

### Method of measurement

Information entered in the patient's delivery record

## 3

### Description

Interval from full cervical dilation to active phase of labor

### Timepoint

Once, after delivery

### Method of measurement

Information entered in the patient's delivery record

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: For termination of pregnancy, 25 micrograms of misoprostol is placed sublingual. According to the uterine contractions, every 3 to 6 hours, 25 micrograms of misoprostol is prescribed up to 4 times, or until the active phase of labor begins, or until the bishop score is 8 or higher, or until the rupture of membrane. In the first and second times of misoprostol administration, an applicator of Stromarin (estrogen) cream is also placed in the posterior part of the vagina.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: For termination of pregnancy, 25 micrograms of misoprostol is placed sublingual. According to the uterine contractions, every 3 to 6 hours, 25 micrograms of misoprostol is prescribed up to 4 times, or until the active phase of labor begins, or until the bishop score is 8 or higher, or until the rupture of membrane.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Yas hospital

##### Full name of responsible person

Fatemeh Golshani

##### Street address

Yas hospital, Nejatollahi St., Karimkhan Blvd.

##### City

Tehran

##### Province

Tehran

##### Postal code

1597856511

##### Phone

+98 21 8608 9089

##### Email

Fgolshahi@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

Name of organization / entity

Tehran University of Medical Sciences

#### Full name of responsible person

Dr. Akbar Fotouhi

#### Street address

Vice-Dean of Research, Tehran University of Medical Sciences, Floor 6, Qods St., Keshavarz Blvd.

#### City

Tehran

#### Province

Tehran

#### Postal code

1416634793

#### Phone

+98 21 6381 9836

#### Email

vcr@tums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Tehran 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

Tehran University of Medical Sciences

##### Full name of responsible person

Fatemeh Golshahi

##### Position

Associate professor

##### Latest degree

Subspecialist

##### Other areas of specialty/work

Gynecology and Obstetrics

##### Street address

Yas hospital, North Nejatollahi St., Karimkhanzand Blvd.

##### City

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##### Province

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##### Postal code

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##### Phone

+98 21 4216 0852

##### Fax

##### Email

fgolshahi@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Fatemeh Golshahi

**Position**

Associate professor

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Subspecialist

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## Person responsible for updating data

### Contact

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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**

No - There is not a plan to make this available

**Informed Consent Form**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

Not applicable

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

All data is potentially shareable after unidentified participants.

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

After the manuscript is published.

**To whom data/document is available**

No limitations.

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

The data is only available to the project manager, Dr. Golshahi, and any analysis must be done with her opinion.

**From where data/document is obtainable**

Dr. Golshahi.

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

Any request must be sent by e-mail with its proposal to Dr. Golshahi.

**Comments**