

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparison of misoprostol with letrozole and without letrozole to induce abortion in the second trimester of pregnancy

#### Protocol summary

##### Summary

This study will be done with a aim to investigate the effect of misoprostol with letrozole to induction abortion in the second trimester of pregnancy. This study is a double-blind clinical trial. The study population will be pregnant women who refer to Imam Reza hospital in Kermanshah city with gestational age of 13 -23 week's, which has indicated termination of pregnancy in drug method and 120 persons will selected and randomly will assigned to two experimental and control groups. In the experimental group letrozole tablets orally at a dose of 2 .5 mg in the form of two tablets given every 12 hours for two days. The beginning of the third day Misoprostol tablets at a dose of 100 mg as 4 tablets every 6 hours, up to 3 doses means 1200 micrograms given vaginally. The control group will receive 8 placebo tablets on two consecutive days, 2 tablets every 12 hours given. Then from the third day, vaginal misoprostol of 100 micrograms as a 4 tablets with a maximum of 3 doses will given every 6 hours. Blood pressure, heart rate and body temperature measured every 2 hours. Fever, nausea, diarrhea, abdominal pain, bleeding and tissue rejection time will also be recorded. Then the time interval between discharge pregnancy products from the first prescribed dose of misoprostol will be recorded for each patient. Patient initial hemoglobin and post-abortion hemoglobin will be measured. In this study for all patients curettage is performed in the operating room routinely and patients' hemoglobin control also will be 6 hours after curettage. Inclusion criteria: gestational age of 13 to 22 with an indication for termination of pregnancy in medical method; Chorioamionitic. Exclusion criteria: patients with a history of caesarean section; Maternal serious chronic systemic and chronic disease.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015123114333N48**

Registration date: **2016-03-02, 1394/12/12**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2016-03-02, 1394/12/12

##### Registrant information

###### Name

Feizollah Foroughi

###### Name of organization / entity

kermanshah University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 83 1821 4653

###### Email address

fforoughi@kums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

##### Expected recruitment start date

2016-01-25, 1394/11/05

##### Expected recruitment end date

2017-07-27, 1396/05/05

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of misoprostol with letrozole and without letrozole to induce abortion in the second trimester of

pregnancy

### Public title

Comparison investigation of the effect of Letrozole misoprostol to induce abortion in the second trimester of pregnancy

### Purpose

Treatment

### Inclusion/Exclusion criteria

Inclusion criteria: Gestational age of 13 to 22 with an indication for termination of pregnancy in medical method; Chorioamionitic. Exclusion criteria: Patients with a history of caesarean section; Maternal serious chronic systemic and chronic disease; Cardiovascular disease.

### Age

From **15 years** old to **45 years** old

### Gender

Female

### Phase

2

### Groups that have been masked

*No information*

### Sample size

Target sample size: **120**

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Double blinded

### Blinding description

### Placebo

Used

### Assignment

Parallel

### Other design features

Randomly by tossing coin

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

##### Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

##### City

Kermanshah

##### Postal code

#### Approval date

2015-01-16, 1393/10/26

#### Ethics committee reference number

45253/7/420/پ

## Health conditions studied

### 1

#### Description of health condition studied

Termination of pregnancy in the second trimester

#### ICD-10 code

O04

#### ICD-10 code description

Medical abortion

## Primary outcomes

### 1

#### Description

Duration of induction to abortion

#### Timepoint

From admission until 48 hours later

#### Method of measurement

Doctor observation

### 2

#### Description

Blood pressure

#### Timepoint

Baseline, every 2 hours, discharge time

#### Method of measurement

Manometer

### 3

#### Description

Heart rate

#### Timepoint

Baseline, every 2 hours, discharge time

#### Method of measurement

By doctor

### 4

#### Description

Temperature

#### Timepoint

Baseline, every 2 hours, discharge time

#### Method of measurement

By thermometer

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

In the experimental group letrozole tablets orally at a dose of 2.5 mg in the form of two tablets given every 12 hours for two days. At the beginning of the third day Misoprostol tablets at a dose of 100 mg as 4 tablets

every 6 hours, up to 3 doses means 1200 micrograms given vaginally.

**Category**

Treatment - Drugs

**2****Description**

The control group will receive 8 placebo tablets on two consecutive days , 2 tablets every 12 hours given. Then on the third day, vaginal misoprostol of 100 micrograms as a 4 tablets every 6 hours with a maximum of 3 doses will given

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Emam Reza Hospital

**Full name of responsible person**

Negin hajiali Akbari

**Street address**

Emam Reza Hospital, Parastar Boulevard

**City**

Kermanshah

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice chancellor for research, Kermanshah University of Medical Sciences

**Full name of responsible person**

Koroush Hamzehee

**Street address**

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

**City**

Kermanshah

**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, Kermanshah 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****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Dr. Anisodole Nankali

**Position**

Obstetricians

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

Emam Reza Hospital, Parastar Boulevard

**City**

Kermanshah

**Postal code****Phone**

+98 83 3427 6301

**Fax****Email**

anankali@kums.ac.ir

**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*