

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The effect of letrozole / misoprostol compared with placebo / misoprostol in success rate of medical abortion

Protocol summary

Summary

Objective: investigation the success rate of Letrozole in combination with Misoprostol in medical abortion by using the synergistic effect of drugs in inducing abortion. Setting and conduct: This study is a prospective clinical trial, double blind and randomization, with control group (placebo). The study will be performed in the Hospitals of Mashhad University of Medical Sciences on pregnant women who are undergoing medical abortion. The randomization is done by using closed envelopes. Inclusion criteria: age over 18 years; twenty weeks gestational age based on ultrasound; hemoglobin over 10 mg/dl; diastolic blood pressure less than 95 mm/hg; no history of thrombolytic, no history of cancer and no history of liver disease. Exclusion criteria: asthma; blood pressure; porphyritic; breast; liver disease; IUD existence; smoking more than twenty cigarettes a day. Participants: Pregnant women Interventions: letrozole / misoprostol. Primary outcome variables: abortion.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017042933680N1**
Registration date: **2017-06-26, 1396/04/05**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-06-26, 1396/04/05

Registrant information

Name

Farideh Golhasani

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2017-03-20, 1395/12/30

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of letrozole / misoprostol compared with placebo / misoprostol in success rate of medical abortion

Public title

The effect of letrozole / misoprostol compared with placebo / misoprostol in success rate of medical abortion

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Upper 18 years old; Twenty weeks gestational age based on ultrasound; Hemoglobin greater than 10 mg/dl; Diastolic blood pressure less than 95 mmHg; No history of thrombolytic, Cancer and liver disease. Exclusion criteria: Asthma; Hypertension; Porphyritic; Breast; liver disease; Having IUD; Smoking upper twenty cigarettes a day.

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **300**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Mashhad University of Medical sciences

Street address

Daneshgah St, Department of Ghoreish

City

Mashhad

Postal code

13944-91388

Approval date

2017-04-26, 1396/02/06

Ethics committee reference number

IR.MUMS.fm.REC.1395.569

Health conditions studied**1****Description of health condition studied**

Medical abortion

ICD-10 code

O08.9

ICD-10 code description

Complication following abortion and ectopic and molar pregnancy, unspecified

Primary outcomes**1****Description**

Abortion

Timepoint

after intervention

Method of measurement

Sonography

Secondary outcomes**1****Description**

Endometrial thickness

Timepoint

after Intervention

Method of measurement

sonography, Less than twenty millimeters is considered as complete abortion and endometrial thickness greater than twenty millimeters is considered as incomplete abortion

Intervention groups**1****Description**

The intervention group will receive daily oral dose of 10 mg letrozole 2 days before hospitalization. Third dose of one will receive in time of hospitalization.

Category

Treatment - Drugs

2**Description**

The control group will receive daily oral dose of 10 placebo 2 days before hospitalization. Third dose of one will receive in time of hospitalization.

Category

Treatment - Drugs

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

Hospital's Teaching of Imam Reza (AS)

Full name of responsible person

Dr Taheri

Street address

Shariati Square. Imam Reza (AS) Hospital

City

Mashhad

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

Mashhad University of Medical Sciences

Full name of responsible person

Marjan Ardakanian

Street address

Daneshgah St, Ghoreishi Department

City

Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Dr.Taheri

Position

Resident of Obstetrics and Gynecology

Other areas of specialty/work

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Dr Farideh Akhlaghi

Position

Assistant professor of Obstetrics and Gynecology

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Master

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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