Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 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
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Iran (Islamic Republic of)
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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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Person responsible for scientific inquiries

Contact

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Dr Farideh Akhlaghi

Position

Assistant professor of Obstetrics and Gynecology

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person

Farideh Golhasani

Position

Master

Other areas of specialty/work

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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