Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Induction of abortion in the first trimester by misoprostol or misoprostol with different dose of letrozol In women referring to Akbarabadi hospital in 1398-1399

Protocol summary

Study aim

Induction of abortion in the first trimester by misoprostol or misoprostol with different dose of letrozol In women referring to Akbarabadi hospital in 1398-1399

Design

Clinical trial with control group with mosaic group, randomized. Phase 2-3, on 114 patients undergoing abortion under 12 weeks, unilateral blindness and used for randomization by randomized block method

Settings and conduct

This clinical trial study is performed in Shahid Akbarabadi Hospital in Tehran. Patients seeking medical abortion under 12 weeks are included in the study. In the first intervention group letrozole 5 mg and misoprostol 800 mg tablets three doses every three hours vaginal, in the second intervention group letrozole 10 mg and misoprostol 800 mg three doses every three hours vaginal and in the control group placebo and misoprostol 800 mg Three doses are given every three hours vaginally.

Participants/Inclusion and exclusion criteria

Inclusion criteria:Age older than 18 years,Gestational age based on ultrasound findings less than 12 weeks,Patient and spouse satisfaction,Lack of systemic diseases such as hypertension, kidney disease,Hemoglobin greater than or equal to 10 g / l, diastolic blood pressure less than 95 mm Hg Exclusion criteria:Having an IUD,Any allergy to letrozole or misoprostol Liver disease, kidney failure, high blood pressure and asthma,Convulsions

Intervention groups

Letrozole 5 mg and misoprostol tablets 800 mg three doses at intervals of three hours vaginal Letrozole 10 mg and misoprostol tablets 800 mg three doses at intervals of three hours vaginal. Placebo and misoprostol tablets 800 mg three doses at intervals of three hours vagina

Main outcome variables

The interval between induction of abortion and the onset of abortion, opening of the internal cervical opening and complete abortion are evaluated in all three groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160523028008N13**
Registration date: **2021-03-21, 1400/01/01**
Registration timing: **prospective**

Last update: **2021-03-21, 1400/01/01**
Update count: **0**

Registration date

2021-03-21, 1400/01/01

Registrant information

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Name of organization / entity
Hamadan University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-05, 1400/02/15

Expected recruitment end date

2021-08-23, 1400/06/01

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Induction of abortion in the first trimester by misoprostol or misoprostol with different dose of letrozol In women referring to Akbarabadi hospital in 1398-1399

Public title
Induction of abortion in the first trimester by misoprostol or misoprostol with different dose of letrozo
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age older than 18 years Gestational age based on ultrasound findings less than 12 weeks Patient and spouse satisfaction Lack of systemic diseases such as hypertension, kidney disease Hemoglobin greater than or equal to 10 g / l, diastolic blood pressure less than 95 mm Hg
Exclusion criteria:
Having an IUD Any allergy to letrozole or misoprostol Liver disease, kidney failure, high blood pressure and asthma Convulsions
Age
From **18 years** old
Gender
Female

Phase
2-3
Groups that have been masked

- Participant

Sample size
Target sample size: **114**
Randomization (investigator's opinion)
Randomized
Randomization description
The patients will be randomly assigned to interventions and control groups using block randomization. For this purpose, we will prepare six sheets of paper, writing on four sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The six paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients are not aware of the type of intervention, so the study is a one-way blind.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Iran University of Medical Sciences
Street address
Iran University of Medical Sciences, Hemmat High Way
City
Tehran
Province
Tehran
Postal code
1168743514
Approval date
2021-02-21, 1399/12/03
Ethics committee reference number
IR.IUMS.FMD.REC.1399.766

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
The interval between induction and abortion beginning and opening of cervical internal os
Timepoint
Until 24 hours after receiving Misoprostol, every 1 hou
Method of measurement
Sonography

2

Description
The interval between induction and complete abortion
Timepoint
Until 24 hours after receiving Misoprostol, every 1 hour
Method of measurement
Sonography

Secondary outcomes

1

Description
Gastrointestinal problems (nausea or vomiting)
Timepoint
From receiving Letrozole until 24 hours after receiving Misoprostol
Method of measurement
Objective

Intervention groups

1

Description
Intervention group: Letrozole 10 mg and misoprostol tablets 800 mg three doses at intervals of three hours vaginal made by Abureyhan Pharmaceutical Company, Iran
Category
Treatment - Drugs

2

Description
Intervention group: Letrozole 5 mg and misoprostol tablets 800 mg three doses at intervals of three hours vaginal made by Abureyhan Pharmaceutical Company, Iran
Category
Treatment - Drugs

3

Description
Control group: Placebo and misoprostol tablets 800 mg three doses at intervals of three hours vaginal made by Abureyhan Pharmaceutical Company, Iran
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Akbar Abadi Hospital
Full name of responsible person
mojgan mokhtari
Street address
shahid Akbar Abadi Hospital, Ferdowsi Station, Molavi st, Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran 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
Iran University of Medical Sciences
Full name of responsible person
Mojgan Mokhtari
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is not a plan to make this available

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available