Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

Comparison the effect of Letrozole plus Misoprostol with Misoprostol alone on induction of first trimester abortion in pregnant women

Protocol summary

Summary

Objectives: Induced abortion is one of the most common subjects which has been investigated widely in obstetrics and gynecology field. The aim of this study is to compare the effect of Letrozole plus Misoprostol with Misoprostol alone on first trimester abortion induction. Design: In this clinical trial, after documentation of general information such as age, weight and medical history, 70 pregnant women who are candidate for therapeutic abortion under 12 weeks of gestational age, will be randomly divided into two groups of control or trial. Setting and conduct: After admitting in the hospital, the patients in the control group will receive Misoprostol vaginally for abortion induction. Letrozole tablet will be given to the patients of the trial group for three days, then the patients will be admitted at the third day and receive Misoprostol vaginally. Major inclusion and exclusion criteria: Pregnant women with 18 to 34 years of age with nonviable pregnancy under 12 weeks from the first day of last menstrual period. Without history of systemic diseases or presence of acute conditions that require any urgent intervention and treatment. Intervention: Receiving Letrozole plus Misoprostol or Misoprostol alone. Main outcome measures (variables): Patients will be monitored for 24 hours after taking Misoprostol and will be evaluated for gastrointestinal side effects and the interval between induction and abortion beginning, opening of cervical internal os and complete abortion.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015050119037N8**
Registration date: **2015-06-01, 1394/03/11**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-06-01, 1394/03/11

Registrant information

Name
Mahdieh Yousef-Zanjani
Name of organization / entity
Qazvin University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2014-11-22, 1393/09/01

Expected recruitment end date

2015-05-22, 1394/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effect of Letrozole plus Misoprostol with Misoprostol alone on induction of first trimester abortion in pregnant women

Public title

Comparison the effect of Letrozole with Misoprostol on induction of first trimester abortion in pregnancy

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Pregnant women with 18 to 34 years of age with nonviable pregnancy under 12 weeks from the first day of last menstrual period. Exclusion criteria: History of systemic diseases or presence of acute conditions that require any urgent intervention and treatment.
Age
From **18 years** old to **34 years** old
Gender
Female

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
In this study the candidate patients for therapeutic abortion under 12 weeks will be randomly divided into one of the groups (trial or control) by usage of colored carts.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Qazvin University of Medical Sciences
Street address
Shahid Bahonar Boulevard
City
Qazvin
Postal code
Approval date
2013-10-15, 1392/07/23
Ethics committee reference number
7931

Health conditions studied

1

Description of health condition studied
Therapeutic Abortion
ICD-10 code
O04
ICD-10 code description
Therapeutic/Medical Abortion (termination of pregnancy)

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 hour
Method of measurement
Physical examination

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
First intervention group (control): Receiving 8 Misoprostol 100 mcg tablets as a single vaginal dose from Abureyhan drug manufacturing company, Iran
Category
Treatment - Drugs

2

Description
Second intervention group (trial): Receiving 4 Letrozole 2.5 mg tablets daily for 3 days (orally), from Abureyhan drug manufacturing company, Iran Plus Receiving 8 Misoprostol 100 mcg tablets as a single vaginal dose from Abureyhan drug manufacturing company, Iran (with third day dose of Letrozole)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kosar Obstetrics and Gynecology Hospital
Full name of responsible person
Dr. Ezzatossadat Haj Seyyed Javadi
Street address
Kosar Street, Ayatollah Taleghani Boulevard
City
Qazvin

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Investigator
Full name of responsible person
Dr. Masoumeh Mohammadi
Street address
Kosar Hospital, Kosar Street, Ayatollah Taleghani Boulevard
City
Qazvin
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Investigator
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
Kosar Obstetrics and Gynecology Hospital
Full name of responsible person
Dr. Masoumeh Mohammadi
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Obstetrics and Gynecology Resident
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Person responsible for scientific inquiries

Contact
Name of organization / entity
Qazvin University of Medical Sciences
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Dr. Ezzatossadat Haj Seyyed Javadi
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Assistant professor
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Email
dr_ seidjavadi@yahoo.com
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