

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

Country

Iran (Islamic Republic of)

Phone

+98 28 3333 6004

Email address

yusefi.mahdieh@yahoo.com

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

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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

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

Position

Obstetrics and Gynecology Resident

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr. Ezzatossadat Haj Seyyed Javadi

Position

Assistant professor

Other areas of specialty/work

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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