

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Evaluation of effect of letrozole with misoprostol in comparison with misoprostol alone in success rate of induced abortion

Protocol summary

Summary

In a study the effect of letrozole in combination with misoprostol on candidates for induced abortion will be assessed. The aim of the study is to find a new protocol to avoid abortion. In this randomized study intervention and control groups will receive two protocols of A or B. Women with pregnancy in 14 or less than 14 weeks and 38 years of age will be included in the study. In intervention group the patients will receive 10 mg/kg letrozole and 4 vaginal tablets (200 µg) of misoprostol for 3 dose. In control group the patients will only receive misoprostol the same way above. In case of no abortion, 48 hours after the last dose of suppository, profuse bleeding will be started or the remnant of the fetus will be confirmed by transvaginal ultrasonography one day after abortion. Hence, the patients will uner go curettage to remove fetus. The the prevalence of complete abortion, the duration of induction to complete expulsion of products of conception, the frequency of the need for surgical abortion, the consumer misoprostol side effects such as nausea, vomiting, diarrhea, headache, dizziness and pain in the lower abdomen will be assessed in both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017011526962N3**

Registration date: **2017-02-10, 1395/11/22**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-02-10, 1395/11/22

Registrant information

Name

Tahereh Behroozi Lak

Name of organization / entity

Educational and Treatment Kowsar Center

Country

Iran (Islamic Republic of)

Phone

+98 44 3223 7077

Email address

behroozilak.t@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research Urmia university of Medical Sciences

Expected recruitment start date

2017-01-20, 1395/11/01

Expected recruitment end date

2018-01-21, 1396/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of effect of letrozole with misoprostol in comparison with misoprostol alone in success rate of induced abortion

Public title

The effect of letrozole in combination with misoprostol on induced abortion success rate

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients more than 18 years of age, pregnancy in 14 or less than 14 weeks (will be on firm by ultrasonography), Hb above 10, diastolic blood

pressure of below 95 mm Hg Exclusion criteria: Adrenal gland failure, cancer, porphyria, thromboembolism, severe hepatic diseases, bronchial asthma, hypertension, breast feeding, hepatic function tests disorders, blood tests disorders, consumption of any medicine

Age

From **18 years** old to **38 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **78**

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

Urmia University of Medical Sciences

Street address

Urmia, Resalat Blvd. the end of Jahad St. Research ward, Setad, Urmia university of medical sciences Urmia Western Azarbaijan Iran, Islamic Republic Of

City

Urmia

Postal code

5714783734

Approval date

2017-01-18, 1395/10/29

Ethics committee reference number

ir.umsu.rec.1395.436

Health conditions studied

1

Description of health condition studied

induced abortion

ICD-10 code

008

ICD-10 code description

Pregnancy with abortive outcome

Primary outcomes

1

Description

Complete abortion

Timepoint

After intervention

Method of measurement

will be on firm by ultrasonography

2

Description

the duration of induction to complete expulsion of products of conception

Timepoint

The interval between the consumer misoprostol I until the abortion

Method of measurement

Hours

Secondary outcomes

1

Description

The need for surgical abortion in the two groups

Timepoint

During intervention

Method of measurement

will be on firm by ultrasonography

2

Description

The consumer misoprostol in two groups

Timepoint

During intervention

Method of measurement

The number of vaginal tablets used

3

Description

Age patients

Timepoint

During intervention

Method of measurement

Year

4

Description

Gestational age

Timepoint

The duration from the last period

Method of measurement

Week

Intervention groups

1

Description

In intervention group the patients will receive 10 mg/kg letrozole and 4 vaginal tablets (200 µg) of misoprostol for 3 dose

Category

Treatment - Drugs

2

Description

Administration of misoprostol alone

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Educational and treatment kowsar center

Full name of responsible person

Tahereh Behroozi Lak

Street address

Urmia university of medical sciences West Azarbajian Iran, Islamic Republic Of

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research Urmia university of medical sciences

Full name of responsible person

Iraj Mohebbi

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Urmia, Resalat Blvd. the end of Jahad St. Research ward, Setad, Urmia university of medical sciences Urmia West Azarbajian Iran, Islamic Republic Of

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urmia

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research Urmia 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

Urmia University of Medical Sciences

Full name of responsible person

Tahereh Behroozi Lak

Position

Assistant Professor

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