

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

Investigating the success rate of aromatase inhibitor (letrozole) in the treatment of ectopic pregnancies compared to methotrexate.

Protocol summary

Study aim

Determination of the success rate of aromatase inhibitor (letrozole) in the treatment of ectopic pregnancy compared to methotrexate

Design

A clinical trial, with parallel groups, double-blind, randomized, phase 2 on 40 patients

Settings and conduct

40 people are selected from among the people who referred to the hospital in whom ectopic pregnancy was proven. Checklist of demographic and laboratory information is completed. Patients will be divided into two equal groups of 20 to receive letrozole or methotrexate. BHCG levels will be checked in both groups on the first day of treatment and on days 4, 7, and 14 after treatment. The selection of patients is done by a doctor other than the researcher, and the researcher is not aware of how the patients are divided based on the type of medicine received. However, the choice of the type of medicine is made based on whether the file number is even or odd, thus, the patient is not aware of the type of medicine received

Participants/Inclusion and exclusion criteria

Entry requirements : 1. Proven ectopic pregnancy 2. The age of the patient is 18-40 years 3. Laboratory standards
Non-entry conditions: 1. Instability of vital signs and occurrence of symptoms based on internal bleeding 2. Presence of surgical indication 3. Contraindications for use of letrozole or methotrexate

Intervention groups

Patients are divided into two equal groups of 20 people to receive letrozole or methotrexate. In the group receiving methotrexate, a single dose of methotrexate will be calculated with a dose of 50 mg per square meter of the body. In the group receiving letrozole, 2.5 mg tablets are prescribed twice a day for 10 consecutive days.

Main outcome variables

BHCG test

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170828035961N2**

Registration date: **2023-07-01, 1402/04/10**

Registration timing: **registered_while_recruiting**

Last update: **2023-07-01, 1402/04/10**

Update count: **0**

Registration date

2023-07-01, 1402/04/10

Registrant information

Name

Farahnaz Mardanian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3693 2380

Email address

mardanian@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-22, 1402/03/01

Expected recruitment end date

2024-05-21, 1403/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the success rate of aromatase inhibitor (letrozole) in the treatment of ectopic pregnancies compared to methotrexate.

Public title

Investigation of the effect of letrozole in the treatment of ectopic pregnancies compared to methotrexate.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Proven ectopic pregnancy (EP) Patient age 18-40 years Serum level (BHCG) beta Human Chorionic Gonadotropin less than 5000 Serum hemoglobin level above 10 Serum platelet level above 150,000

Exclusion criteria:

unstability of vital signs and occurrence of symptoms related to internal bleeding. The presence of surgical indications (viewing the fetal heart, abdominal EP (ectopic pregnancy), size above 3.5 cm, EP rupture and abdominal bleeding) Contraindications for use of letrozole or methotrexate (chronic kidney, liver and blood diseases, immunodeficiency, breastfeeding, active lung disease, peptic ulcer, simultaneous intrauterine pregnancy, drug interactions, severe drug sensitivity)

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, 40 eligible ectopic pregnant will be selected randomly. Then the letters A and B are written on 20 sheets and each one is placed in an envelope. Each patient is then asked to choose one of the envelopes. Depending on the selected envelope, the patient is assigned to one of two groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, two drugs, letrozole and methotrexate, are placed in coded packages by the pharmacy manager and delivered to the researcher, who is unaware of the type of each. Medications are prescribed. Also, the person recording the clinical and basic information of the patients as well as the statistical analyst will not be aware of the type of intervention.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee of Isfahan University of Medical Sciences.

Street address

Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq

City

Esfahan

Province

Isfahan

Postal code

8179964167

Approval date

2021-10-06, 1400/07/14

Ethics committee reference number

IR.MUI.MED.REC.1400.559

Health conditions studied

1

Description of health condition studied

Ectopic pregnancy.

ICD-10 code

O00.9

ICD-10 code description

Ectopic pregnancy, unspecified

Primary outcomes

1

Description

Serum levels of beta Human Chorionic Gonadotropin (BHCG)

Timepoint

The first day of treatment and days 4, 7 and 14 after treatment

Method of measurement

BHCG test.

Secondary outcomes

1

Description

Serum levels of liver enzymes

Timepoint

The first day of treatment and 7 days after that

Method of measurement

Blood test

2

Description

Serum levels of creatinine

Timepoint

The first day of treatment and 7 days after that

Method of measurement

Blood test

3

Description

Serum hemoglobin level

Timepoint

The first day of treatment and 7 days after that

Method of measurement

Blood test

4

Description

Counting the number of blood platelets

Timepoint

The first day of treatment and 7 days after that

Method of measurement

Blood test

5

Description

Anti-Müllerian hormone serum level

Timepoint

The first day of treatment and 3 months after that

Method of measurement

Blood test

6

Description

Drug side effects

Timepoint

while taking medication

Method of measurement

check list

7

Description

History of ectopic pregnancy

Timepoint

The beginning of treatment

Method of measurement

check list

8

Description

Number of pregnancies

Timepoint

The beginning of treatment

Method of measurement

check list

Intervention groups

1

Description

Intervention group: In the group receiving methotrexate, a single dose of methotrexate with a dose of 50 mg per square meter of the body will be calculated and injected intramuscularly or subcutaneously.

Category

Treatment - Drugs

2

Description

Intervention group: In the group receiving letrozole, 2.5 mg tablets are prescribed twice a day for 10 consecutive days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Shahid Beheshti Hospital.

Full name of responsible person

Farhanaz Mardanian

Street address

Shahid Beheshti Hospital, Shahid Motahari Street

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2

Recruitment center

Name of recruitment center

Al-Zahra Hospital

Full name of responsible person

Dr. Farhanaz Mardanian

Street address

Al-Zahra Hospital; Sofeh boulevard

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fmardani2005@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Gholamreza Asgari

Street address

Vice Chancellor for Research, School of Medicine,
Hezar Jarib Street, Isfahan.

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8174673461

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dean@med.mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Farhanaz Mardanian.

Position

Professor, specialist doctor of the academic staff.

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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Position

Professor, specialist doctor of the academic staff

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

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Position

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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 no further information

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