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

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Iran (Islamic Republic of)

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+98 31 3693 2380

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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 20sheets 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
Isfehan

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
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2

Recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr. Gholamreza Asgari
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Vice Chancellor for Research, School of Medicine, Hezar Jarib Street, Isfahan.
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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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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