

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effect of letrozole in the treatment of ectopic pregnancy and comparing its therapeutic effect with methotrexate

Protocol summary

Study aim

Evaluating the efficacy of letrozole in treating ectopic pregnancy and comparing its effect with methotrexate treatment

Design

Clinical trial with control group, with parallel groups, without blinding, randomized, phase 3 on 75 patients, random table was used for randomization.

Settings and conduct

As a patient diagnosis in the women's department of Waliasr Hospital (AJ) of Tehran University of Medical Sciences

Participants/Inclusion and exclusion criteria

A pregnant woman diagnosed with an ectopic pregnancy is a candidate for drug treatment/

Intervention groups

The first group received methotrexate in a single dose
The second group received letrozole in a 10-day period, once a day
The third group received letrozole for a period of 5 days, 2 pills a day

Main outcome variables

BHCG level and rate of ectopic pregnancy treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220902055855N1**

Registration date: **2023-04-13, 1402/01/24**

Registration timing: **prospective**

Last update: **2023-04-13, 1402/01/24**

Update count: **0**

Registration date

2023-04-13, 1402/01/24

Registrant information

Name

saeedeh Eslami khotbesara

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 4428 0054

Email address

saeedeh_eslami2001@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-22, 1402/03/01

Expected recruitment end date

2024-02-20, 1402/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of letrozole in the treatment of ectopic pregnancy and comparing its therapeutic effect with methotrexate

Public title

Investigating the effect of letrozole in the treatment of ectopic pregnancy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients diagnosed with ectopic pregnancy who are candidates for medical treatment

Exclusion criteria:

Unstable patients and candidates for surgical treatment
The presence of fetal heart activity in the gestational sac

BHCG level is more than 3000

Age
From **18 years** old to **45 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **75**

Randomization (investigator's opinion)
Randomized

Randomization description
In this non-blinded clinical trial with the control group patients randomly will divide into 3 groups according to the above items. There are 25 patients in each group using the randomization method of the table of numbers of vital statistics reference books in such a way that the numbers 1 to 25 belong to the first group, and the numbers 26 to 50 belong to the second group and the numbers 51-75 belong to the third group. The analyst is blinded to the group allocation, but the researcher and the patient are not blinded in this study.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of tehran university of medical science

Street address

Keshavarz Blvd., Imam Khomeini Hospital (RA),
Women's Department of Valiasr Hospital

City

Tehran

Province

Tehran

Postal code

14197 33141

Approval date

2022-07-19, 1401/04/28

Ethics committee reference number

IR.TUMS.IKHC.REC.1401.093

Health conditions studied

1

Description of health condition studied

Ectopic pregnancy

ICD-10 code

O00

ICD-10 code description

Ectopic pregnancy

Primary outcomes

1

Description

decreased bhcg trend

Timepoint

First, seventh, fourteenth day

Method of measurement

Use of defined laboratory criteria

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group received letrozole with the brand name Letrofem 2.5 mg orally by Iran Hormon Company for a period of 10 days, two oral doses in the morning at the same time.

Category

Treatment - Drugs

2

Description

The first intervention group received letrozole with the brand name Letrofem 2.5 mg orally by Iran Hormon company for a period of 5 days, three times a day in the morning.

Category

Treatment - Drugs

3

Description

The control group received methotrexate from Razavi Pharmaceutical Company, 50 mg per square meter of body surface as a single intramuscular dose.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital (RA) complex

Full name of responsible person

Saeedeh Eslami Khotbesara

Street address

Keshavarz Boulevard, Imam Khomeini Hospital (RA)

City

Tehran

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Postal code

14197 33141

Phone

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Email

saedeh_eslami2001@yahoo.com

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Saeedeh Eslami Khotbesara

Street address

Tehran, keshavarz Blvd, Imam Khomeini Hospital

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331411497

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saedeh_eslami2001@yahoo.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

10

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**

Tehran University of Medical Sciences

Full name of responsible person

Azadeh Tarafdari manshadi

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Azadeh Tarafdari manshadi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact**Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Saeedeh Eslami Khotbesara

Position

Obstetrics& Gynecology Surgery Resident

Latest degree

Medical doctor

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

Due to not starting the study and uncertain results of the study.

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

Undecided - It is not yet known if there will be a plan to make this available