

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

use of Letrozole And Metotrexate for treatment of ectopic pregnancy compared with Metotrexate at Shahid akbarabadi hospital

Protocol summary

Study aim

Specific Objectives of the Dissertation use of Letrozole and metotrexate for treatment of ectopic pregnancy compared with metotrexate

Design

Admission of Patients with EP and divided two group .first group treatment by metotrexate And second group treatment by metotrexate + letrozole And compare two groups with outcome to decrease BHCG Titration

Settings and conduct

In Gynecology Ward Admission of Patients with EP and divided two group .first group treatment by Metotrexate 50 mg/m² And second group treatment by Metotrexate + letrozole 10mg in first day second day third day and measuring BHCG Titration in 4 and 7 day And compare two groups with outcome to decrease BHCG Titration by 15% and check of BHCG weekly to immeasurable BHCG

Participants/Inclusion and exclusion criteria

Inclusion Criteria 18= \leq Age \leq 50 β HCG \leq 5000 ectopic pregnancy Positive(Sonography Criteria) Normal LFT Stable of vital Signe Ep \leq 3.5 cm Absent of fetal heart rate No Contraindicated of MTX Exclusion Criteria Breast feeding positive FHR

Intervention groups

letrozole and metotrexate user for treatment of ectopic pregnancy compared with only metotrexate

Main outcome variables

First outcome :measuring BHCG Titration weekly to immeasurable BHCG second outcome:Treatment of complication

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230403057811N1**

Registration date: **2023-07-08, 1402/04/17**

Registration timing: **registered_while_recruiting**

Last update: **2023-07-08, 1402/04/17**

Update count: **0**

Registration date

2023-07-08, 1402/04/17

Registrant information

Name

Narjes Farahani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5592 9540

Email address

morel607@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-21, 1402/02/01

Expected recruitment end date

2023-08-23, 1402/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

use of Letrozole And Metotrexate for treatment of ectopic pregnancy compared with Metotrexate at Shahid akbarabadi hospital

Public title

Effect of Letrozole in Ectopic Pregnancy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

ectopic pregnancy Positive(Sonography Criteria)
Ep<=3.5 cm Absent of fetal heart rate βHCG <=5000
stable of vital signe

Exclusion criteria:

treatment of ectopic pregnancy by surgical fetal heart
rate Positive Sensitivity of Letrozole breast feeding
Failuer of kidney and liver function

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Single blind

Placebo

Not used

Assignment

Parallel

Other design features

no

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committee of school medicine -Iran
Univercity of medical sciences

Street address

Tehran Hemat highway next to Milad tower

City

Tehran

Province

Tehran

Postal code

۱۳۹۶۱۴۳۵

Approval date

2021-11-23, 1400/09/02

Ethics committee reference number

IR.IUMS.FMD.REC.1400.502

Health conditions studied

1

Description of health condition studied

Ectopic Pregnancy

ICD-10 code

O00.9

ICD-10 code description

Ectopic pregnancy

Primary outcomes

1

Description

Decrease off BHCG Titration

Timepoint

In 4,7 Day if Decrease off BHCG Titration Check off BHCG
Weekly

Method of measurement

ELISA Method

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1 : Patient by Ectopic Pregnancy
Treatment by only MTX

Category

Treatment - Drugs

2

Description

Intervention group 2: Patient by Ectopic Pregnancy
Treatment by MTX And Letrozole

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Akbarabadi Hospital

Full name of responsible person

Narjes Farahani

Street address

Akbarabadi Hospital Bagh Ferdos Station , Molavi Ave
,Tehran

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1168743514

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Reza Falak

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Iran University of Medical Sciences next to Milad
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Grant name

Grant code / Reference number

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

No

Title of funding source

Research Assistant Iran 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

Iran University of Medical Sciences

Full name of responsible person

Narjes Farahani

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Narges Farahani

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

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Resident

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Medical doctor

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

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

Study Protocol

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

Statistical Analysis Plan

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

Informed Consent Form

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

Clinical Study Report

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

Analytic Code

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

Data Dictionary

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