Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

Comparison evaluation of letrozol metoretoxate treatment in patients with ectopic pregnancy

Protocol summary

Study aim
Comparison of treatment with letrozole and methotrexate in patients with ectopic pregnancy in Kowsar Qazvin hospital

Design
Clinical trials include a 24-person group receiving mtx for ep treatment and a 24-person group receiving letrozole for ep treatment. Without control group, parallel groups, data collection is blind. Random allocation is based on software allocation ra software, phase 2 on 48 patients.

Settings and conduct
This study will begin at Kowsar Hospital in Qazvin in 1401. Patients receiving MTX receive 50 mg / m2 of intramuscular methotrexate. We measure BHCG on the fourth day of the seventh day and then every week until zero. CBC, LFT and BUN measurements are also on the fourth day 0 and every week until zero BHCG. The other group will receive 2.5 mg of letrozole every 12 hours for 10 days. BHCG, CBC, LFT and BUN are the same as the previous group

Participants/Inclusion and exclusion criteria
Women with ectopic pregnancies can participate in this study if they have the following conditions: The adnexal mass is less than four centimeters Absence of active intra-abdominal bleeding The person is healthy in terms of kidney health diseases Lack of fetal heart activity Hcg B level is less than 5000 Do not breastfeed The conditions for not entering the study are as follows: The disease is a candidate for surgery Patient's dissatisfaction with participating in the study

Intervention groups
In this study, the intervention was therapeutic use of letrozole instead of methotrexate to treat EP in order to prevent liver and blood complications and to prevent adverse effects on patients' ovarian reserve.

Main outcome variables
The rate of BHCG drop on the seventh day compared to the fourth day; BHCG zeroing time; The effect of medication on blood platelets; The effect of drug therapy on liver enzymes; The effect of medication on the patient's BUN and Cr

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220411054497N1**
Registration date: **2022-10-03, 1401/07/11**
Registration timing: **prospective**

Last update: **2022-10-03, 1401/07/11**
Update count: **0**

Registration date
2022-10-03, 1401/07/11

Registrant information

Name
Sanaz Maleki

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 28 3323 6374

Email address
sanazmlk97@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-10-23, 1401/08/01

Expected recruitment end date
2023-02-20, 1401/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison evaluation of letrozol metoretoxate treatment in patients with ectopic pregnancy

Public title
Evaluation of the effectiveness of letrozole in EP treatment

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Absence of active intra-abdominal bleeding Adnexal mass below four centimeters The person is healthy in terms of liver and kidney disease B-HCG levels should be less than 5000 The patient should not breastfeed

Exclusion criteria:
If the patient is a candidate for surgery If the patient does not consent to participate in the study

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

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **48**

Randomization (investigator's opinion)
Not randomized

Randomization description

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 of committee of Qazvin University of Medical sciences

Street address
Bahonar

City
Qazvin

Province
Qazvin

Postal code
3419759811

Approval date
2021-02-22, 1399/12/04

Ethics committee reference number
IR.QUMS.REC.1399.484

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
B-HCG

Timepoint
0 day fourth day and seventh day

Method of measurement
Blood test and B-HCG check request

2

Description
Duration of zeroing of B-HCG in the two groups of letrozole and methotrexate

Timepoint
From day one of B-HCG assay until the B-HCG marker is zero

Method of measurement
Blood test and B-HCG check request

Secondary outcomes

1

Description
Hbg

Timepoint
The first day of referral, the fourth day and the seventh day and then weekly until the BHCG is zero

Method of measurement
Taking blood tests and checking CBC

2

Description
WBC

Timepoint
The first day of referral, the fourth day and the seventh day and then weekly until the BHCG is zero

Method of measurement
Taking blood tests and checking CBC

3

Description
platelets
Timepoint
The first day of referral, the fourth day and the seventh day and then weekly until the BHCG is zero
Method of measurement
Taking blood tests and checking CBC

4

Description
LFT
Timepoint
The first day of referral, the fourth day and the seventh day and then weekly until the BHCG is zero
Method of measurement
Blood test and blood biochemistry check

5

Description
BUN
Timepoint
The first day of referral, the fourth day and the seventh day and then weekly until the BHCG is zero
Method of measurement
Blood test and blood biochemistry check

Intervention groups

1

Description
The intervention group: includes a group of 24 people receiving letrozole for the treatment of EP, after explaining the benefits and side effects of both treatment methods and obtaining informed consent from them, 2.5 mg tablets every twelve hours for ten days receive letrozole
Category
Treatment - Drugs

2

Description
The intervention group: includes a group of 24 people receiving methotrexate for the treatment of EP, who after explaining the benefits and complications of both treatment methods and obtaining informed consent from them, methotrexate ampoules with a dose of fifty mg per square meter It is done for them in a muscular way
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kosar Hospital
Full name of responsible person
Dr. Fatemeh Lalouha
Street address
Taleghani Ave.
City
Qazvin
Province
Qazvin
Postal code
3415613176
Phone
+98 28 3323 6380
Email
Lalooha44@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Dr.Lalooha
Street address
Taleghani Ave
City
Qazvin
Province
Qazvin
Postal code
3415613176
Phone
+98 28 3323 6380
Email
sanazmlk97@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Qazvin University of Medical Sciences Research Assistant
Proportion provided by this source
100
Public or private sector
Private
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
Qazvin University of Medical Sciences
Full name of responsible person
Sanaz Maleki

Position
Medical Intern
Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
Street address
Bahonar Ave.
City
Qazvin
Province
Qazvin
Postal code
3419759811
Phone
+98 28 3333 6001
Email
sanazmlk97@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Fatemeh Lalouha
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Kosar Hospital, Taleghani Ave.
City
Qazvin
Province
Qazvin
Postal code
3415613176
Phone
+98 28 3323 6374
Email
lalooha44@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Sanaz Maleki
Position
medical intern
Latest degree
A Level or less
Other areas of specialty/work
Others
Street address
Qazvin university of Medical science, Bahonar Ave.
City
Qazvin
Province
Qazvin
Postal code
3419759811
Phone
+98 28 3333 6001
Email
sanazmlk97@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is 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
Not applicable
Title and more details about the data/document
Only information from the study participants will be published that is relevant to the outcome of the study and that they have been informed of their consent prior to the start of the study.
When the data will become available and for how long
The access period started at the beginning of 1401 and continues until the examination of 24 patients receiving letrozole treatment
To whom data/document is available
This information is available in the early stages for researchers and university-level research supervisors
Under which criteria data/document could be used
This information is available in the early stages for researchers and university-level research supervisors
From where data/document is obtainable
To receive comments, you can refer to the main project manager and then the executive project manager
What processes are involved for a request to access data/document
Submitting a request to the research director After reviewing by the project manager, a request to the research vice chancellor of the university
Comments