

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

The effects of adding letrozole to methotrexate on the management of tubal ectopic pregnancies at Yas Hospital

Protocol summary

Study aim

Evaluation of the effects of using letrozole and methotrexate in comparison with the use of placebo and methotrexate on the management of tubal ectopic pregnancies

Design

Controlled Clinical Trial, with parallel groups, triple blinded, randomized by random allocation method

Settings and conduct

Yas Hospital patients

Participants/Inclusion and exclusion criteria

Inclusion criteria: - Age: 18 - 40 years old - Ectopic tubal pregnancy - BetaHCG levels less than 5000 IU/L

Exclusion criteria: - Fetal heart rate - hemodynamic instability - Significant abdominal pain - History of allergic reactions to methotrexate - History of allergic reactions to letrozole and other aromatase inhibitor agents - Hypercholesterolemia - Heterotopic pregnancy

Intervention groups

Adding letrozole or placebo to methotrexate treatment

Main outcome variables

BetaHCG level changes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130808014301N2**

Registration date: **2020-07-01, 1399/04/11**

Registration timing: **prospective**

Last update: **2020-07-01, 1399/04/11**

Update count: **0**

Registration date

2020-07-01, 1399/04/11

Registrant information

Name

zahra rezaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8890 0002

Email address

rezaizah@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-07-22, 1399/05/01

Expected recruitment end date

2021-02-18, 1399/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of adding letrozole to methotrexate on the management of tubal ectopic pregnancies at Yas Hospital

Public title

The effects of adding letrozole to methotrexate on the management of tubal ectopic pregnancies

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Tubal ectopic pregnancies BetaHCG level less than 5000 IU/L

Exclusion criteria:

Fetal heart rate Hemodynamic instability Significant abdominal pain History of allergic reactions to

methotrexate History of allergic reactions to letrozole and other aromatase inhibitor agents hypercholesterolemia Liver enzymes abnormalities Abnormal renal function tests Heterotopic pregnancies

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation, there are 45 small envelopes containing letter A and 45 small envelopes in the same shape containing letter B in a bag; and for each patient one envelope is selected randomly.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo and letrozole tablets are in the same shape and depending on the patient's group name (A or B) are given to the patient's nurse by the responsible doctor; thus the patient and the nurse are blinded. In addition, outcome observer physician, data collector, and data analyzer are blinded and they don't know which intervention is used for each group.

Placebo

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 Sciences

Street address

Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town

City

Tehran

Province

Tehran

Postal code

1598718311

Approval date

2020-05-20, 1399/02/31

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1399.070

Health conditions studied

1

Description of health condition studied

Tubal ectopic pregnancy

ICD-10 code

O00.1

ICD-10 code description

Tubal pregnancy

Primary outcomes

1

Description

Blood beta-HCG level changes

Timepoint

Before, and 4 and 7 days after beginning of the treatment, then weakly until the negative test

Method of measurement

blood test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The main treatment is a single dose of 50 mg/m² intramuscular methotrexate injection. By the day of methotrexate injection, the interventional treatment as Abureyhan Co. 2.5 milligram letrozole tablets - 4 tablets daily - is prescribed orally for seven days.

Category

Treatment - Drugs

2

Description

Control group: The main treatment is a single dose of 50 mg/m² intramuscular methotrexate injection. By the day of methotrexate injection, the interventional treatment as Abureyhan Co. placebo tablets - 4 tablets daily - is prescribed orally for seven days.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Yas Hospital

Full name of responsible person

Dr. Zahra Rezaei

Street address

Yas Hospital, Ostad Nejatolahi Ave., Karimkhan Blvd.

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rezaizah@tums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Atefe Ahmadi

Street address

Deputy research of TUMS, Fifth floor of Central building of Tehran University of Medical Sciences, Qods Ave., Keshavarz Blvd.

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Dr. Zahra Khalaj Sereshki

Position

fellowship student

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Yas Hospital, Ostad Nejatolahi Ave., Karimkhan Blvd.

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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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