

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

The effect of letrozole on endometrial thickness in endometriosis patients who are candidate for IVF

Protocol summary

Study aim

Comparison the effects of letrozole on endometrial thickness and fertility outcome in endometriotic patients candidate for IVF

Design

Double blind clinical trial phase 3 ,with parallel groups which were chosen with envelop pocket A or B by patients for randomization.

Settings and conduct

All infertile endometriotic patients who are Candidate for IVF will be allocated in letrozole or placebo groups from day2-7 of cycle,when the fix antagonist cycle of ovarian stimulation is started.Both patients and caregivers are blinded regarding the groups, and they were randomized with envelope containing A or B letter.

Participants/Inclusion and exclusion criteria

Inclusion criteria:Infertile patients; IVF Candidate; endometriosis Exclusion criteria:Endometrial lesions; hypersensitivity to letrozole; liver dysfunction

Intervention groups

Intervention group: Two tablets of letrozole will be used from second day of induction ovulation and continued for five days then induction continued by fixed antagonist protocol Control group : Two tablets of placebo will be used from second day of induction ovulation and continued for five days then induction continued by fixed antagonist protocol

Main outcome variables

Clinical pregnancy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20091012002576N26**

Registration date: **2022-09-13, 1401/06/22**

Registration timing: **prospective**

Last update: **2022-09-13, 1401/06/22**

Update count: **0**

Registration date

2022-09-13, 1401/06/22

Registrant information

Name

Fatemeh Davari Tanha

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-22, 1401/06/31

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of letrozole on endometrial thickness in endometriosis patients who are candidate for IVF

Public title

The effect of letrozole on endometrial thickness in endometriosis IVF patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
IVF Candidate History of endometriosis

Exclusion criteria:
pathologic lesion in endometrial cavity pathologic lesion in endometrial cavity; hypersensitivity to letrozole; liver disease liver disease

Age
From **20 years** old to **40 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization rule: First 40 letters A and 40 letters B are written on special papers that are not marked inside. Then all of them are placed in a bag and for each patient, after obtaining informed consent, a paper is removed randomly and without replacement, and based on the letter written on it, the desired intervention is performed for the patients. In addition, interventions A (case group) or B (control group) are determined by a lot.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients and care providers are blinded regarding the case and control groups with using placebo that is the same as letrozole regarding form and taste.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethic committee of Tehran University of Medical sciences

Street address
Deputy of research-6th floor-central building of Tehran University of Medical sciences-Ghods avenue-Keshavarz Blvd-Tehran-Iran

City
Tehran

Province

Tehran

Postal code
۱۵۹۷۸۱۵۹۷۸۱۵

Approval date
2022-09-11, 1401/06/20

Ethics committee reference number
IR.TUMS.MEDICINE.REC.1401.467

Health conditions studied

1

Description of health condition studied
Infertility

ICD-10 code
N97.8

ICD-10 code description
Female infertility of other origin

Primary outcomes

1

Description
Endometrial thickness

Timepoint
At the day of triggering(5days after ending intervention)

Method of measurement
By vaginal ultrasound

Secondary outcomes

1

Description
Chemical pregnancy

Timepoint
Two weeks after embryo transfer

Method of measurement
BhCG test

2

Description
Clinical pregnancy

Timepoint
Four weeks after embryo transfer

Method of measurement
Visualisation fetal heart rate by vaginal ultrasound

Intervention groups

1

Description
Intervention group: Two tablets of letrozole 2.5 mg(Aboureiha pharmaceutical) will be used from second day of induction ovulation and continued for five days then induction continued by fixed antagonist protocol at 5th day of induction and continued till follicle 18mm will be occurred in TVS, endometrial thickness will

be evaluated, trigger of ovulation and OPU will be scheduled for next 36 hours .

Category

Treatment - Drugs

2

Description

Control group: Two tablets of placebo will be used from second day of induction ovulation and continued for five days then induction continued by fixed antagonist protocol at 5th day of induction and continued till follicle 18mm will be occurred in TVS, endometrial thickness will be evaluated, trigger of ovulation and OPU will be scheduled for next 36 hours .

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

IVF Clinic of Yas Hospital

Full name of responsible person

Fatemeh Davari Tanha

Street address

Yas hospital;North Nejatollahi avenue;Karim Khan zand Bridge;Villa street

City

Tehran

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Tehran

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1579781597878

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Email

Fatedavtanha@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Fatemeh Davari Tanha

Street address

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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

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

Fatemeh Davari Tanha

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

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Person responsible for updating data

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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

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