Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Jul 2026

Investigating the effect of letrozole on endometrial thickness in IVF candidate patients at Yas Hospital infertility clinic

Protocol summary

Study aim
Determination of the effect of letrozole on endometrial thickness in transvaginal ultrasound in IVF candidate patients

Design
Phase 3 clinical trial with a control group, with a parallel design, double-blind, is conducted on 100 patients using the random allocation rule.

Settings and conduct
This randomized study will be performed on 100 patients with IVF indication in Yas Hospital with a convenient sampling method. This is a double-blind study, the patient and analyzer do not know the type of treatment.

Participants/Inclusion and exclusion criteria
Inclusion criteria: - Women diagnosed with infertility - Women who are candidates for IVF Exit criteria: - Pregnancy - Presence of endometrial pathological lesions - The person's lack of consent to participate in the study - Intolerance of letrozole in the patient - Presence of letrozole contraindications in patients such as liver diseases

Intervention groups
The case group receives 2.5 mg of letrozole daily from the third day of the menstrual cycle for 5 days.

Main outcome variables
The thickness of the uterine endometrium,Biochemical pregnancy,Clinical pregnancy

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20120104008611N14**
Registration date: **2023-07-19, 1402/04/28**
Registration timing: **prospective**

Last update: **2023-07-19, 1402/04/28**
Update count: **0**

Registration date
2023-07-19, 1402/04/28

Registrant information

Name
Hamideh Pakniat

Name of organization / entity
Qazvin University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-07-23, 1402/05/01

Expected recruitment end date
2023-09-23, 1402/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of letrozole on endometrial thickness in IVF candidate patients at Yas Hospital infertility clinic

Public title
the effect of letrozole on endometrial thickness

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women diagnosed with infertility IVF candidate women

Exclusion criteria:

pregnancy Presence of endometrial pathological lesions The person's lack of consent to participate in the study Intolerance of Letrozole in the patient Presence of Letrozole contraindications in patients such as liver diseases

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation rule: First, 50 letters A and 50 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 patient. In addition, interventions A (letrozole) or B (clomiphene) are determined by a lot.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is performed double-blind, the participants, and the analyzer do not know the type of treatment. The participants, because of placebo usage, do not know the type of their treatment. Also, the analyzer does not know about the treatment group codes in the SPSS datasheet.

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

Pour Sina St

City

Tehran

Province

Tehran

Postal code

1598718311

Approval date

2022-04-21, 1401/02/01

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1401.467

Health conditions studied

1

Description of health condition studied

Female Infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

Assess endometrial thickness

Timepoint

The second or third day of the menstrual cycle

Method of measurement

sonography

Secondary outcomes

1

Description

Biochemical pregnancy

Timepoint

Once, 14 days after fetus transfer

Method of measurement

Blood sampling

2

Description

Clinical pregnancy

Timepoint

Once, 6 to 8 weeks after embryo transfer

Method of measurement

Observation of pregnancy sac and heart rate on ultrasound

Intervention groups

1

Description

Intervention group:Patients receive letrozole 2.5 mg daily for 5 days from the third day of the menstrual cycle.

Category

Treatment - Drugs

2

Description
Control group: People receive daily placebo for 5 days from the third day of the menstrual cycle.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Yas hospital
Full name of responsible person
Hamideh Pakniat
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
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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
Qazvin University of Medical Sciences
Full name of responsible person
Hamideh Pakniat
Position
Asistant Professor, Department of Obstetrics and Gynecology Qazvin University of Medical Sciences
Latest degree
Specialist
Other areas of specialty/work
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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

No - There is not a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data is potentially shareable after unidentified participants.

When the data will become available and for how long

After manuscript published

To whom data/document is available

No limitations

Under which criteria data/document could be used

The data is only available to the project manager, Dr. Pakniat, and any analysis must be done with her opinion.

From where data/document is obtainable

Dr. Pakniat

What processes are involved for a request to access data/document

Any request must be made in writing and accompanied by a proposal with an ethics code under the supervision of Dr. Pakniat

Comments