

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Comparison of letrozole administration to stimulate ovulation in IUI cycles by two methods of 20 mg single dose and 5 days

Protocol summary

Study aim

Comparison of ovarian response to ovulation stimulation with letrozole tablets by 20 mg and 5-day methods

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 2 on 80 patients. Excel software "rand" function was used for randomization.

Settings and conduct

Patients visit one to three cycles a day and receive one of the treatments randomly. Then the patient performs transvaginal ultrasound on days 9 to 11 of the cycle. The size of the follicles and the thickness of the endometrium are checked. The number of HMG ampoules is prescribed and again two days later the patient will have an ultrasound. The number of observed follicles and the diameter of the largest observed follicle will be recorded. If a follicle above 14 mm is seen, the patient is followed by a follicle in the size of 19-18 mm HCG and 36 hours later IUI is performed. Then the results will be recorded and compared in two groups. The amount of HMG consumed will also be recorded will be. The patient is given a letter to refer to Mahdih Hospital in case of any emergency problems such as abdominal pain, nausea, vomiting, etc.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age of 40-20 years old; at least one year of infertility; no underlying disease. The spermogram was within acceptable range for IUI and at least one fallopian tube was open. Exclusion criteria: history of allergy to letrozole and other aromatase inhibitors; cabergoline and other ergot derivatives; history of pelvic surgery and the presence of any factor other than infertility.

Intervention groups

Patients are divided into two random groups and will be given 20 mg of letrozole single dose or 5 times daily letrozole 3 times.

Main outcome variables

Number of follicles per day 9 to 11 cycles; diameter of

the largest follicle; HMG consumption; incidence of pregnancy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220412054511N1**

Registration date: **2022-12-10, 1401/09/19**

Registration timing: **prospective**

Last update: **2022-12-10, 1401/09/19**

Update count: **0**

Registration date

2022-12-10, 1401/09/19

Registrant information

Name

Elham Hashemi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6605 6115

Email address

helham260@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-04, 1401/11/15

Expected recruitment end date

2023-09-06, 1402/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of letrozole administration to stimulate ovulation in IUI cycles by two methods of 20 mg single dose and 5 days

Public title

Letrozole for IUI

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Have a history of at least one year of infertility Absence of underlying disease including abnormal thyroid stimulating hormone prolactin Spermogram within acceptable range for IUI At least one fallopian tube is open.

Exclusion criteria:

History of allergy to letrozole and other aromatase inhibitors History of allergy to cabergoline and other ergot derivatives History of pelvic surgery

Age

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

Gender

Female

Phase

2

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple individual randomization using randomization software

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double-blind and the patient and the researcher do not know which group the patient belongs to.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences, Koodakiar street, Tehran

City

Tehran

Province

Tehran

Postal code

146367

Approval date

2022-11-05, 1401/08/14

Ethics committee reference number

IR.SBMU..MSP.REC.1401.375

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

Ovarian response (the number of follicle with size more than 14 millimeter)

Timepoint

The day 9 to 11 of menstruation cycle

Method of measurement

Vaginal ultrasound

2

Description

Ovarian response (the size of biggest follicle)

Timepoint

The day 9 to 11 of menstruation cycle

Method of measurement

Vaginal ultrasound

3

Description

Endometrial thickness

Timepoint

The day 9 to 11 of menstruation cycle

Method of measurement

Vaginal ultrasound

4

Description

The number of HMG ampoules required

Timepoint

from day 11 to 13 menstruation cycle

Method of measurement

Medical record

Secondary outcomes

1

Description

Pregnancy (Positive BHCG test)

Timepoint

Two weeks after IUI (intra uterine insemination)

Method of measurement

Blood test

2

Description

Abortion

Timepoint

During 3 months after pregnancy confirmation

Method of measurement

Getting out of pregnancy products (direct observation or ultrasound)

Intervention groups

1

Description

Intervention group: Women candidates for IUI who will receive a single dose of Letrozole 20 mg tablet

Category

Treatment - Drugs

2

Description

Control group: Women candidates for IUI who will receive 5 mg of Letrozole tablets daily for 5 days from the third day of the cycle (common approach)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mahdiyeh Hospital

Full name of responsible person

Zahra Heidar

Street address

Shishe Gar khaneh Alley, Fadaian Islam Ave, Shoosh Sq, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1185817311

Phone

+98 21 5506 2628

Email

mahdiyeh_hospital@sbm.ac.ir

Web page address

https://mmc.sbm.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zaraghi

Street address

Shahid Beheshti University of Medical Sciences, Koodakiar street

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1985717443

Phone

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Email

info@sbm.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Elham Hashemi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

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Elham Hashemi

Position

Resident

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not 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

Only part of the data such as information about the main outcome or the like can be shared.

When the data will become available and for how long

6 months after publication

To whom data/document is available

For researchers working in academic and scientific institutions and people working in industry

Under which criteria data/document could be used

The data of this study can be used for meta-analysis.

From where data/document is obtainable

The applicant for the information must send an email in English containing the name and how to use this data to the executor's email address. helham260@gmail.com

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

The applicant for the information must send an email in English containing the name and how to use this data to the executor's email address. Information will be sent to them within 10 working days of sending the email.

Comments