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 Mahdieh 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
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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

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Email

mahdiyeh_hospital@sbmu.ac.ir

Web page address

https://mmc.sbmu.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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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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Position
Resident

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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