

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 May 2026

Impact of letrozol on improvement oocyte quality and IVF outcome in infertile patients underwent controlled ovarian stimulation

Protocol summary

Study aim

Impact of letrozol on oocyte quality and IVF success

Design

Two arm parallel group randomized ,double blind clinical trial with placebo control group to assess oocyte quality and IVF outcome with letrozol prescription in antagonist protocol ovarian stimulation. The sample size is 110 patient in each intervention and control group with block randomization.

Settings and conduct

This a double blind clinical trial in IVF field in Vali- e -Asr infertility center. Infertile women who IVF candidate simultaneous with introduce ovulatory stimulating drugs received in intervention group, letrozol and in control group placebo until trigger day.36 hours after triggering ovum pickup is performed under general anesthesia .Metaphase 2 number and quality is determined by embryologist. participants, researcher ,embryologist and statistics are blind to study groups. With use of placebo and packing of drugs and placebo and ascertained study groups by someone outside the study , participant and researcher became blind .Evaluating the outcome is performed by researcher and embryologist who are blind.All data is delivered to statistic by researcher who is blind to study groups

Participants/Inclusion and exclusion criteria

Inclusion criteria:Infertile women who IVF condidate which 40 years old or younger and underwent antagonist protocol for ovulation stimulation Exclusion criteria : patient with cancer , use of other IVF protocol for ovulation stimulation except antagonist protocol

Intervention groups

In intervention group,infertile women candidate for IVF, who underwent antagonist protocol ,received letrozol 5 milligram daily from day of initiation of gonadotropine drugs until day of trigger injection. In control group,infertile women instead of letrozle received placebo, the other process is the same between two groups.

Main outcome variables

Number of Metaphase 2 oocyte

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200328046881N1**

Registration date: **2020-04-05, 1399/01/17**

Registration timing: **registered_while_recruiting**

Last update: **2020-04-05, 1399/01/17**

Update count: **0**

Registration date

2020-04-05, 1399/01/17

Registrant information

Name

Mahin Bandarian

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

mahbandarianmd@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-04, 1399/01/16

Expected recruitment end date

2020-11-20, 1399/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Impact of letrozol on improvement oocyte quality and IVF outcome in infertile patients underwent controlled ovarian stimulation

Public title

Impact of letrozol on oocyte quality and IVF success

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Infertile patient that IVF candidate with 40 years old or less use of antagonist protocol for IVF

Exclusion criteria:

Patient with cancer Use of IVF protocol except antagonist protocol

Age

From **17 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **220**

More than 1 sample in each individual

Number of samples in each individual: **2**

Serum specimen for estradiol and testosterone measurement _Follicular fluid

Randomization (investigator's opinion)

Randomized

Randomization description

Block Randomization In this study all of participation, consist of 220 individuals , dividing to 55 blocks with 4 persons . In each block, equal number of intervention and control groups exist. These 55 blocks , are in 55 different arrangements of intervention and control groups

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants after signed informed constant , randomly assigned to either study groups and received drug or placebo which is thoroughly identical and same package. patients are blind to which groups that belong to. Researcher is blind by preparing and packing of drugs and placebo and ascertaining control or intervention groups is done by someone outside the study. Study outcomes partly is done by researcher who blind to study groups and other part by embryologist who is blind to study groups. All data will deliver to statistics by researcher who blind to study groups.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee in the research of Imam Khomeini Hospital Complex, Tehran University of Medical Sci

Street address

End of Keshavarz Blvd., Dr. Gharib St., Imam Khomeini Hospital Complex

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Province

Tehran

Postal code

1419733141

Approval date

2020-03-14, 1398/12/24

Ethics committee reference number

IR.TUMS.IKHC.REC.1399.004

Health conditions studied**1****Description of health condition studied**

Infertility

ICD-10 code

N97.0

ICD-10 code description

Female infertility associated with anovulation

2**Description of health condition studied**

Infertility

ICD-10 code

N97.1

ICD-10 code description

Female infertility of tubal origin

3**Description of health condition studied**

Infertility

ICD-10 code

N97.2

ICD-10 code description

Female infertility of uterine origin

4**Description of health condition studied**

Infertility

ICD-10 code

N97.8

ICD-10 code description

Female infertility of other origin

5**Description of health condition studied**

Infertility

ICD-10 code

N97.9

ICD-10 code description

Female infertility, unspecified

6**Description of health condition studied**

Infertility

ICD-10 code

Z31.81

ICD-10 code description

Encounter for male factor infertility in female patient

Primary outcomes**1****Description**

Number of metaphase 2 oocyte

Timepoint

After ovum pick up

Method of measurement

Number of metaphase 2 by counting metaphase 2 oocyte by embryologist

Secondary outcomes**1****Description**

Oocyte quality

Timepoint

After ovum pick up

Method of measurement

Based on morphology of different parts of metaphase 2 oocyte which determined by embryologist

2**Description**

Oocyte maturation rate

Timepoint

After ovum pickup

Method of measurement

Number of metaphase2 oocytes divided to number of picked up oocytes

3**Description**

Fertilization rate

Timepoint

After injection of sperm to metaphase 2 oocyte

Method of measurement

Number of 2PN divided to number of metaphase 2 oocyte that injected

4**Description**

Clinical pregnancy rate

Timepoint

After embryo transfer

Method of measurement

Number of pregnancy that confirmed with presence of gestational sac in ultrasonography divided to number of fresh or frozen embryo transfer cycles

Intervention groups**1****Description**

Intervention group: Simultaneous with introduce stimulation ovulation drugs , tablet letrozol 2.5 milligram (Iran hormone company)two time a day until trigger day will receive.

Category

Treatment - Drugs

2**Description**

Control group: This group simultaneous with introduce ovulation stimulation drugs , received two tablets of letrozol placebo (Iran hormone company) a day until trigger day

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Vali- e -asr hospital

Full name of responsible person

Masoumeh Masoumil

Street address

Vali - e -asr hospital , Imam khomeini institute , Eastern bagher khan Ave , Chamran High way , Tohid Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraeian

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P.O Box 1417653761 , Vice Chancellor for Research and Technology, 6th floor, Central Organization of Tehran University of Medical Sciences, Keshavarz Blvd.

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vcr@tums.ac.ir

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

Mahin Bandarian

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

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Latest degree

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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

No - There is not 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