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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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 testostrone measurement _Folicular 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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Tehran

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
Street address
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
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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