

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation of efficacy of Letrozole on the duration and severity of Ovarian hyperstimulation syndrome

Protocol summary

Study aim

Evaluation of efficacy of Letrozole on the duration and severity of Ovarian hyperstimulation syndrome

Design

A clinical trial with a control group, with parallel groups, blinded, randomized, phase 2 on 40. A random number table was used for randomization.

Settings and conduct

The study in the infertility ward of Afzalipour Hospital in Kerman was conducted as a clinical trial in 1399 (2020) in which 20 women who were in the IVF cycle and received ovarian stimulant drugs and the symptoms of ovarian hyperstimulation syndrome are considered as patients prone to severe ovarian hyperstimulation syndrome and are selected for inclusion in the study. These patients are scheduled to freeze all fetuses and are given 2.5 mg letrozole tablets daily for up to 10 days, and clinical and laboratory signs and symptoms are charted. On the other hand, another 20 women with the same characteristics as the 20 women in the case were selected as controls, except that they were routinely treated for severe ovarian hyperstimulation syndrome and were not given letrozole alone. Then, the two groups are then compared in terms of length of recovery and severity of ovarian hyperstimulation syndrome.

Participants/Inclusion and exclusion criteria

Enter condition : Having Ovarian hyperstimulation syndrome
Not enter condition : Lack of incidence of hyperstimulation syndrome after receiving ovarian stimulant drug due to infertility / Patient dissatisfaction to participate in the study

Intervention groups

Intervention group: Prescription of Letrozole tablet 2.5 mg from Abu Reihan company orally daily for 10 days along with routine treatment of ovarian hyperstimulation syndrome
Control group: Evaluation of tests and sonography of the control group based on the case that they have received only routine treatment of ovarian hyperstimulation syndrome.

Main outcome variables

Duration of Ovarian hyperstimulation syndrome

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141008019464N2**

Registration date: **2020-12-21, 1399/10/01**

Registration timing: **retrospective**

Last update: **2020-12-21, 1399/10/01**

Update count: **0**

Registration date

2020-12-21, 1399/10/01

Registrant information

Name

Victoria Habibzadeh

Name of organization / entity

Kerman University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 342322250

Email address

v_habibzadeh@kmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-22, 1398/06/31

Expected recruitment end date

2020-09-21, 1399/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of efficacy of Letrozole on the duration and severity of Ovarian hyperstimulation syndrome

Public title
Evaluation of efficacy of Letrozole on the duration and severity of Ovarian hyperstimulation syndrome

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Having Ovarian hyperstimulation syndrome
Exclusion criteria:
Lack of incidence of hyperstimulation syndrome after receiving ovarian stimulant drug due to infertility Patient dissatisfaction to participate in the study

Age
No age limit

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Random number table: Each person in the community is assigned a two-digit code and then randomly 20 numbers of two-digit number range selected from the random number table and based on the selected code, the case group is determined and similarly choose the control group.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of kerman University of Medical Sciences
Street address
No 6 Hezaroyekshab Ave

City
Kerman
Province
Kerman
Postal code
7618614937
Approval date
2020-09-19, 1399/06/29
Ethics committee reference number
IR.KMU.AH.REC.1399.083

Health conditions studied

1

Description of health condition studied
Ovarian hyperstimulation syndrome
ICD-10 code
N98.1
ICD-10 code description
Hyperstimulation of ovaries

Primary outcomes

1

Description
Duration of Ovarian hyperstimulation syndrome
Timepoint
2-3 weeks after intervention
Method of measurement
laboratory tests

Secondary outcomes

1

Description
Liver enzymes
Timepoint
2 weeks after intervention
Method of measurement
laboratory tests

2

Description
Hematocrit
Timepoint
2 weeks after intervention
Method of measurement
laboratory tests

3

Description
Ratio of urea to creatinine
Timepoint
2 weeks after intervention
Method of measurement
laboratory tests

4

Description

Evacuation of ascites

Timepoint

7 & 14 days after intervention

Method of measurement

Number of ascites Evacuations

5

Description

Existence of thrombosis

Timepoint

7 & 14 days after intervention

Method of measurement

Ultrasound

6

Description

Ovary size

Timepoint

2 weeks after intervention

Method of measurement

Ultrasound

7

Description

Shortness of breath

Timepoint

7 & 14 days after intervention

Method of measurement

history

Intervention groups

1

Description

Intervention group: Prescription of Letrozole tablet 2.5 mg from Abu Reihan company with chemical formula C₁₇H₁₁N₅ 1 orally daily for 10 days along with routine treatment of ovarian hyperstimulation syndrome and evaluation of drug effect by testing and sonography within 3 weeks Since the start of letrozole

Category

Treatment - Drugs

2

Description

Control group: Evaluation of tests and sonography of the control group based on the case that they have received only routine treatment of ovarian hyperstimulation syndrome.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Afzalipoor Hospital

Full name of responsible person

Victoria Habibzadeh

Street address

Afzalipoor Hospital, Zendan Square

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Kerman

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Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Kerman University of Medical Sciences

Full name of responsible person

Fatemeh Hassani

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Tahmasbabad Square, Ebnesina Street

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7619813159

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info.knrc@kmu.ac.ir

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Kerman 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

v_habibzadeh@kmu.ac.ir

Contact

Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Victoria Habibzadeh
Position
Assistant Professor
Latest degree
Subspecialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Afzalipoor Hospital, Zendan Square
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Person responsible for scientific inquiries

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Person responsible for updating data

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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

Undecided - It is not yet known if there will be 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