

# 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 C<sub>17</sub>H<sub>11</sub>N<sub>5</sub> 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

##### City

Kerman

##### Province

Kerman

##### Postal code

۷۶۱۶۹۱۳۹۱۱

##### Phone

+98 34 3223 5011

##### Email

v\_habibzadeh@kmu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Kerman University of Medical Sciences

##### Full name of responsible person

Fatemeh Hassani

##### Street address

Tahmasbabad Square, Ebnesina Street

##### City

Kerman

##### Province

Kerman

##### Postal code

7619813159

##### Phone

+98 34 3226 3719

##### Email

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  
**City**  
Kerman  
**Province**  
Kerman  
**Postal code**  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
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**Full name of responsible person**  
Victoria Habibzadeh  
**Position**  
Assistant Professor  
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**Email**

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Kerman University of Medical Sciences  
**Full name of responsible person**  
Victoria Habibzadeh  
**Position**  
Assistant Professor  
**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

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