Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

Evaluation of the effect of letrozole in the prevention of ovarian hyperstimulation syndrome in patients at risk of treatment with ovulation-stimulating drugs

Protocol summary

Study aim
Determination of the effect of letrozole in the prevention of ovarian hyperstimulation syndrome in treatment with ovulation-stimulating drugs

Design
Randomised, superiority, parallel group trial. Randomisation was centralised and computerised with excel software rand function.

Settings and conduct
The study was performed at the Infertility Center of Isfahan University of Medical Sciences. Diagnosis of polycystic ovaries was made according to Rotterdam criteria, including two of the three items of hyperandrogenism disorder, chronic anovulation and polycystic ovary appearance in morphological examination with transvaginal ultrasound (TVS). Lab tests including FSH, LH, progesterone, estradiol (E2) and Anti-Müllerian hormone were performed. Ultrasound assessment was performed to measure the number of ovarian follicles with a size of 2 -10 mm and evaluation the thickness of the uterine endometrium on 3th day of the menstrual cycle. Then the GNRH Antagonist treatment protocol was performed for patients in both case and control groups.

Participants/Inclusion and exclusion criteria
Patients with polycystic ovaries and fertility disorders

Intervention groups
Intervention group: Five daily doses of recombinant follicle-stimulating hormone 150 Unit/day with Manogan drug 75 Unit/day with Letrozole 5 mg/daily. Control group: Five daily doses of recombinant follicle-stimulating hormone 150 Unit/day with Manogan drug 75 Unit/day.

Main outcome variables
Reduced occurrence of ovarian hyperstimulation syndrome

General information

Reason for update
Expected sample size increase

Acronym

IRCT registration information
IRCT registration number: **IRCT20180313039085N1**
Registration date: **2021-04-10, 1400/01/21**
Registration timing: **retrospective**

Last update: **2021-11-25, 1400/09/04**
Update count: **1**

Registration date
2021-04-10, 1400/01/21

Registrant information

Name
Tayeb Ramim

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 6683 0007

Email address
tramim@razi.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-03-20, 1399/01/01

Expected recruitment end date
2021-03-21, 1400/01/01

Actual recruitment start date
2020-03-20, 1399/01/01

Actual recruitment end date
2021-03-21, 1400/01/01

Trial completion date

2021-03-21, 1400/01/01

Scientific title
Evaluation of the effect of letrozole in the prevention of ovarian hyperstimulation syndrome in patients at risk of treatment with ovulation-stimulating drugs

Public title
Evaluation of the effect of letrozole in the prevention of ovarian hyperstimulation syndrome

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Candidate for treatment with ovarian superovulation drugs history of one year of infertility at least Body mass index less than 25 kg/m2 Antimullerian hormone levels higher than 5 ng/ml

Exclusion criteria:
History of any hormone therapy during the previous three months History of allergy to letrozole and other aromatase inhibitors History of heart disease History of kidney disease History of liver disease History of endocrine diseases

Age
From **20 years** old to **40 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **40**
Actual sample size reached: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Sampling was non-probabilistic and easy. Then patients were randomly divided into four groups: 40 in the letrozole treatment group and 40 in the letrozole-free group. In this randomization method, quadruple therapy blocks (with 10 probabilities) were randomly moved back and forth, and a balanced random list of two treatment groups was obtained with the aim that if the total number of samples was not complete, both groups would be equal.

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 Isfahan University of Medical Sciences

Street address
Hezar Jerib street, Isfahan University of Medical Sciences, Isfahan, Iran

City
Isfahan

Province
Isfehan

Postal code
8174673461

Approval date
2021-02-09, 1399/11/21

Ethics committee reference number
IR.MUI.MED.REC.1399.1031

Health conditions studied

1

Description of health condition studied
Hyperstimulation of ovaries

ICD-10 code
N98.1

ICD-10 code description
Hyperstimulation of ovaries

Primary outcomes

1

Description
Hyperstimulation of ovaries

Timepoint
Two weeks after starting treatment

Method of measurement
Mild, Moderate, Severe

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Five daily doses of recombinant follicle-stimulating hormone 150 Unit/day with Manogan drug 75 Unit/day with Letrozole 5 mg/daily.

Category
Treatment - Drugs

2

Description

Control group: Five daily doses of recombinant follicle-stimulating hormone 150 Unit/day with Manogan drug 75 Unit/day.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrat Maryam Infertility Center of Isfahan University of Medical Sciences

Full name of responsible person

Keihaneh Asasi

Street address

Isfahan University of Medical Sciences, Hezar Jerib street, Isfahan, Iran

City

Isfahan

Province

Isfehan

Postal code

8174673461

Phone

+98 31 3668 0048

Email

tayebramim@yahoo.com

Web page address

https://mui.ac.ir/fa

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Keihaneh Asasi

Street address

Isfahan University of Medical Sciences, Hezar Jerib street, Isfahan, Iran

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Keihaneh Asasi

Position

fellowship

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Isfahan University of Medical Sciences, Hezar Jerib street, Isfahan, Iran

City

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Postal code

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Phone

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Email

tayebramim@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

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Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
Confidentiality of patient data

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
No - There is not 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