

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

The effect of ovarian stimulation with and without letrozole in improves in vitro fertilization outcome in low responder patients

Protocol summary

Summary

The objective of this study is to determine the effect of table letrozol on improves in vitro fertilization outcome in low responder patients. This study, clinical trials, single-blind, single center are conducted in Arash women's hospital. Among women scheduled for IVF, 160 women will participated in this study (based on inclusion criteria). Inclusion criteria: infertile women with less than 3 oocyte; AMH <1, AFC <5 oocyte in each ovarian. Exclusion criteria include women with other causes of infertility. Participants will allocated in two equal groups. In intervention group, gonadotropins (150 units FSH and hmg) and 5 mg letrozole will used for ovarion stimulation. In control group, ovarian stimulation gonadotropins (150 units FSH and hmg) without letrozole will used for ovarion stimulation. Implantation and pregnancy rate, number of ovums and thickness of endometrium in both groups will compared with each other.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201701291952N8**

Registration date: **2017-09-19, 1396/06/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-09-19, 1396/06/28

Registrant information

Name

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Name of organization / entity

Tehran University of Medical sciences

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Recruitment status

Recruitment complete

Funding source

Tehran university of Medical Science

Expected recruitment start date

2017-02-03, 1395/11/15

Expected recruitment end date

2017-09-07, 1396/06/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of ovarian stimulation with and without letrozole in improves in vitro fertilization outcome in low responder patients

Public title

Assessment the effect of ovarian stimulation with and without letrozole in IVF/ICSI outcomes.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: infertile women with less than 3 oocyte; AMH <1, AFC <5 oocyte in each ovarian. Exclusion criteria: Other causes of infertility

Age

From **15 years** old to **50 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 160

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single 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 Tehran University of Medical Science

Street address

Tehran University of Medical Science, Qods Street, Keshavarz Boulevard

City

Tehran

Postal code

Approval date

2016-12-17, 1395/09/27

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1395.1245

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

Clinical pregnancy

Timepoint

3 weeks after embryo transfer

Method of measurement

Ultrasonography

Secondary outcomes

1

Description

Implantation

Timepoint

14 days after embryo transfer

Method of measurement

serum level of BHCG

Intervention groups

1

Description

In intervention group, gonadotropins (150 units FSH and hmg) and 5 mg letrozole will be prescribed in the first 5 days of ovarian stimulation cycle.

Category

Treatment - Drugs

2

Description

In control group, p, gonadotropins (150 units FSH and hmg) will be prescribed in the first 5 days of ovarian stimulation cycle.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Arash Women Hospital

Full name of responsible person

Zohreh Lavasani

Street address

Arash hospital, Rashid street, Tehranpars, Resalat highway

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research, Tehran University of Medical Science

Full name of responsible person

Dr Masoud Younesian

Street address

Tehran University of Medical Science, Qods street, Keshavarz boulevard

City

Tehran

Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice Chancellor for research, Tehran University of Medical Science
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty