

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

To Evaluate Effects of Adding Letrozole To GnRh Antagonist In Pregnancy Outcome of Poor Ovarian Responders Candidate For InVitro Fertilization or IntraCytoplasmic Sperm Injection And Comparing It With Pregnancy Outcome of Poor Ovarian Responders Treated By GnRh Antagonist Alone

Protocol summary

Summary

In this prospective double blind clinical trial at Jaame_Zanan Hospital to assess effects of adding letrozole to GnRh antagonist in treatment outcome of ovarian poor responders candidates for InVitro Fertilization or IntraCytoplasmic Sperm Injection, 70 patients will be enrolled. Inclusion criterias are: infertile females who are referred to Jaame_Zanan Hospital for infertility treatment and candidate for InVitro Fertilization or IntraCytoplasmic Sperm Injection; females diagnosed as ovarian poor responders; females aged over 30 years old. Exclusion criterias are: females having all inclusion criterias but having no consent to enter the project; aged over 50 years old; showing hypersensitivity reactions, serious or intolerable side effects of letrozole(although these reactions are so rare); endocrine disorders such as thyroid malfunction or hyperprolactinemia or diabetes; previous ovarian surgery; follicles larger than 10millimeteres at third day of menstrual cycle; having a history of ovarian hyper stimulation in previous ART cycle; uncorrected mullerian anomaly; active renal or hepatic diseases. 70 participants will be divided in two arms, each containing of 35 patients. All participants in both intervention and control groups will receive 225 IU Follicle_Stimulating Hormone plus 150 IU hMG starting at third day of their menstrual cycles and dose is adjusted according to the patients' response by undergoing serial transvaginal sonography and serum estradiol measurements. In intervention arm Letrozole 2.5 mg/day is added from day 3 to day 7. Then oocytes are punctured, fertilization will occur and embryos are transferred to uterine. It should be emphasized that method of oocyte puncture, fertilization and embryo transfer is the same between two groups of patients. Finally treatment outcomes will be compared in intervention(letrozole plus

GnRh antagonist) and control(GnRh antagonist alone) arms. Treatment outcome measures are: number of oocytes retrieved, number of embryos transferred, endometrial thickness, total gonadotropin dose, cancellation rate, clinical pregnancy rate and implantation rate.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014101919578N1**

Registration date: **2015-02-06, 1393/11/17**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-02-06, 1393/11/17

Registrant information

Name

Firoozeh Akbari Asbagh

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8890 0002

Email address

maeb@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2013-06-18, 1392/03/28

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

To Evaluate Effects of Adding Letrozole To GnRh Antagonist In Pregnancy Outcome of Poor Ovarian Responders Candidate For InVitro Fertilization or IntraCytoplasmic Sperm Injection And Comparing It With Pregnancy Outcome of Poor Ovarian Responders Treated By GnRh Antagonist Alone

Public title

To Assess Effects Of Letrozole In Infertility Treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Infertile female who are referred to InVitro Fertilization Department of Jaame_Zanan Hospital candidates for InVitro fertilization or IntraCytoplasmic Sperm Injection; females aged over 30 years old; females diagnosed as poor ovarian responders. Females should have at least one of listing criterias to be classified as poor responders: previous canceled cycle due to poor ovarian response in an InVitro fertilization or IntraCytoplasmic Sperm Injection cycle (defined as having 3 or less oocytes retrieved or serum estradiol less than 500 pg/ml), serum Follicle_Stimulating Hormone over 10 U/ml and age above 40 years old. Exclusion criterias are: Infertile females having all inclusion criterias but do not wish to be included in the project; females who show letrozole hypersensitivity reactions or serious intolerable side effects of letrozole; females over 50 years old; having endocrine disorders such as thyroid dysfunction, hyperprolactinemia or diabetes; previous ovarian surgery; having a follicle larger than 10 mm at third day of menstrual cycle; history of OHSS in previous ART cycle; uncorrected Mullerian anomaly; active renal or hepatic diseases.

Age

From **30 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Other

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Tehran University of Medical Sciences

Street address

Medical Ethics and History of medicine Research Center building, fourth floor, no.21, 16 Azar street, Keshavarz Boulevar, Tehran, Iran.

City

Tehran

Postal code**Approval date**

2013-06-15, 1392/03/25

Ethics committee reference number

315/5495

Health conditions studied**1****Description of health condition studied**

poor ovarian response

ICD-10 code

N00_N99

ICD-10 code description

R00_R99

Primary outcomes**1****Description**

oocytes retrieved number

Timepoint

at the end of ovarian stimulation cycle

Method of measurement

oocyte retrieved containing both metaphase1 and 2 counted under microscopic examination by genetician

2**Description**

embrios transferred

Timepoint

at the end of cycle after 3-day growth of invitro

Method of measurement

counting embrios under microscopic examination by genetician

3

Description

endometrial thickness

Timepoint

on the day of hCG administration

Method of measurement

measured by transvaginal sonography by gynecologist

4

Description

total gonadotropin dose

Timepoint

after oocyte puncture

Method of measurement

number of 75 IU gonadotropin ampules used till oocyte puncture

Secondary outcomes

1

Description

clinical pregnancy rate per cycle

Timepoint

at the end of project

Method of measurement

SPSS software

2

Description

clinical pregnancy rate per embryo transfer

Timepoint

at the end of project

Method of measurement

SPSS software

3

Description

implantation rate per cycle

Timepoint

at the end of project

Method of measurement

SPSS software

4

Description

implantation rate per embryo transfer

Timepoint

at the end of project

Method of measurement

SPSS software

5

Description

cancellation rate per cycle

Timepoint

at the end of project

Method of measurement

SPSS software

Intervention groups

1

Description

In control group ovarian stimulation will be done by using 225 IU Follicle-Stimulating Hormone(Gonal-F, MERC, Italy) and 150 IU human Menopausal Gonadotropine(Pergonal, Serono, Switzerland) started at third day of menstruation. Serial transvaginal sonography and serum estradiol measurement are done to assess ovarian response and adjust gonadotropin dose per patient. Certolix(Certotide, Serono, Switzerland) 0.25 milligrams daily subcutaneously will be added when at least there is a 14 mm follicle. When at least two 17 mm follicles are developed 10000 IU human Chorionic Gonadotropin(Pregnyl, Organon, Netherland) is injected intramuscularly. Oocytes are punctured 35 to 36 hours later and then fertilization will occur via invitro Fertilization or Intracytoplasmic Sperm Injection and then embryos of best quality will be transferred into uterine on third day of their development. Finally pregnancy outcome will be compared between two groups.

Category

Treatment - Drugs

2

Description

In intervention group ovarian stimulation will be done by using 225 IU Follicle-Stimulating Hormone(Gonal-F, MERC, Italy) and 150 IU human Menopausal Gonadotropine(Pergonal, Serono, Switzerland) started at third day of menstruation. In this group Letrozole 2.5 mg/d(Letrozole, AbuReyhan, Iran) is added from menstrual days 3rd to 7th too. Serial transvaginal sonography and serum estradiol measurement are done to assess ovarian response and adjust gonadotropin dose per patient. Certolix(Certotide, Serono, Switzerland) 0.25 milligrams daily subcutaneously will be added when at least there is a 14 mm follicle. When at least two 17 mm follicles are developed 10000 IU human Chorionic Gonadotropin(Pregnyl, Organon, Netherland) is injected intramuscularly. Oocytes are punctured 35 to 36 hours later and then fertilization will occur via invitro Fertilization or Intracytoplasmic Sperm Injection and then embryos of best quality will be transferred into uterine on third day of development. Finally pregnancy outcome will be compared between two groups.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

IVF Department of Jaame_Zanan Hospital

Full name of responsible person

Seyyede Mojgan Ghalandarpoorattar

Street address

Jaame_Zanan Hospital, Northern Ostad Nejatollahi Avenue, Tehran, Iran.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Firuzeh Akbariasbagh

Street address

Tehran University of Medical Sciences, Poorsina street, Keshavarz Boulevar, Tehran, Iran.

City

Tehran

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

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

Contact

Name of organization / entity

Jaame_Zanan Hospital

Full name of responsible person

Seyyede Mojgan Ghalandarpoorattar

Position

MD, Gynecology resident

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Jaame_Zanan Hospital

Full name of responsible person

Firuzeh Akbariasbagh

Position

MD, Gynecologist, Infertility fellowship

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Position

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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