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 Fertillization or IntraCytoplasmic Sperm Injection And Comparing It With Pregnancy Outcome of Poor Ovarian Responders Treated By GnRh Antsgonist 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 Fertillization or IntraCytoplasmic Sperm Injection, 70 patients will be enrolled. Inclusion criterias are: infertile females who are reffered to Jaame_Zanan Hospital for infertility treatment and candidate for InVitro Fertillization 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 hypersensivity reactions, serious or intolerable side effects of letrozole(although these reactions are so rare); endocrine diorders such as thyroid malfunction or hyperprolactienemia or diabetes; previous ovarian surgery; follicles larger than 10millimeteres at third day of menstural cycle; having a history of ovarian hyper stimulation in previous ART cycle; uncorrected mullerian anomaly; active renal or hepatic diseases. 70 participants will be devided in two arms, each containing of 35 patients. All participants in both intervention and control groups will recieve 225 IU Follicle_Stimulating Hormone plus 150 IU hMG starting at third day of their menstural 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 oovocyetes are punctured, fertillization will occurred and embrios are transfered to uterine. It should be emphasized that method of oovocyte puncture, fertillization and emberio 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 oovocytes retrieved, number of emberios 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 Fertillization or IntraCytoplasmic Sperm Injection And Comparing It With Pregnancy Outcome of Poor Ovarian Responders Treated By GnRh Antsgonist Alone

Public title
To Assess Effects Of Letrozole In Infertility Treatment
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion Criteria: Infertile female who are reffered to InVitro Fertillization Department of Jaame_Zanan Hospital candidates for InVitro fertillization 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 cancled cycle due to poor ovarian response in an InVitro fertillization or IntraCytoplasmic Sperm Injection cycle (defined as having 3 or less oovocytes 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 hypersensivity 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 menstural 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 Universiy 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
oovocyte 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 sonograghy by gynecologist

4

Description
total gonadotropin dose
Timepoint
after oovocyte puncture
Method of measurement
number of 75 IU gonadotropin ampules used till oovocyte puncture

Secondary outcomes

1

Description
clinical pregnancy rate per cycle
Timepoint
at the end of project
Method of measurement
SPSS softeware

2

Description
clinical pregnancy rate per emberio transfer
Timepoint
at the end of project
Method of measurement
SPSS softeware

3

Description
implantation rate per cycle
Timepoint
at the end of project
Method of measurement
SPSS softeware

4

Description
implantation rate per emberio transfer
Timepoint
at the end of project
Method of measurement
SPSS softeware

5

Description
cancelation rate per cycle
Timepoint
at the end of project
Method of measurement
SPSS softeware

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, Swithszerland) started at third day of mensturation. Serial transvaginal sonography and serum estradiol measuement are done to assess ovarian response and adjust gonadotropin dose per patient. Certolix(Certotide, Serono, swithszerland) 0.25 miligrams 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 Chrionic Gonadotropin(Pregnyl, Organon, Netherland) is injected trasmuscularly. Oovocytes are punctured 35 to 36 hours later and then fertilization will ocurred via invitro Fertillization or IntraCytoplasmic Sperm Injection and then embrios of best quality will be transferred into uterine on third day of their developement. 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, Swithszerland) started at third day of mensturation. In this group Letrozole 2.5 mg/d(Letrozole, AbuReyhan, Iran) is added from menstural days 3rd to 7th too. Serial transvaginal sonography and serum estradiol measuement are done to assess ovarian response and adjust gonadotropin dose per patient.certolix(Certotide, Serono, swithszerland) 0.25 miligrams 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 Chrionic Gonadotropin(Pregnyl, Organon, Netherland) is injected trasmuscularly. Oovocytes are punctured 35 to 36 hours later and then fertilization will ocurred via invitro Fertillization or IntraCytoplasmic Sperm Injection and then embrios of best quality will be transferred into uterine on third day of developement. 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 rezident

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Jaame_Zanan Hospital

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Position

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Person responsible for updating data

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Name of organization / entity

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Other areas of specialty/work

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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