Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jun 2026

Comparative study between three methods of ovulation stimulation, conventional, mild stimulation and combining the stop GnRH agonist with letrozole priming in outcome of poor responders in Assisted Reproductive Technology (ART)

Protocol summary

Study aim
A comparative study of three methods of ovulation stimulation for poor responders in ART

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 150 patients in three groups. people in each group, we will use the Restricted randomization method of the block randomization method, so that from 15 blocks of 6, including 2 to A, 2 to B and 2 to C Will be formed

Settings and conduct
After undergoing the IVF cycle, individuals are randomly assigned to one of three methods of stimulating ovulation from the third day of menstruation. Isfahan Shahid Beheshti Hospital

Participants/Inclusion and exclusion criteria
Inclusion criteria: poor responders with criteria of 3 and 4 poseidone. Exclusion criteria: Patients was infected with coronavirus during the cycle, patients who do not respond to drug and do not have follicle after drug. patients who have received drug incorrectly during the cycle.

Intervention groups
The first group is given 300 gonadotropins. then HCG 5000 is given after looking at least two follicles above 17 mm. In the second group, from the second day of menstruation letrozole is given for 5 days and 150 mg of gonadotropin. after two follicles above 17 mm, the trigger is made with two HCG 5000s. In the third group, from the previous 21 days of the GNRH agonist, 250 micrograms are given daily until the onset of menstruation. With the onset of menstruation, letrozole is given 2.5 mg daily for one to five days, and a single FSH is given from day 5 of menstruation. After two follicles above 17 mm, HCG trigger is given HCG with GNRH

Main outcome variables
Comparison of the average number of oocytes obtained and the rate of chemical pregnancy, frequency of IMPLANTATION, frequency of CILINICAL PREGNANCY, frequency of ONGOING PREGNANCY is studied in three study groups.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110908007513N17**
Registration date: **2022-05-04, 1401/02/14**
Registration timing: **registered_while_recruiting**

Last update: **2022-05-04, 1401/02/14**
Update count: **0**

Registration date
2022-05-04, 1401/02/14

Registrant information

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Hatav Ghasemi Tehrani
Name of organization / entity
Isfahan University of Medical Sciences
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-04-16, 1401/01/27
Expected recruitment end date
2022-06-17, 1401/03/27
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative study between three methods of ovulation stimulation, conventional, mild stimulation and combining the stop GnRH agonist with letrozole priming in outcome of poor responders in Assisted Reproductive Technology (ART)

Public title
Comparative study of between three methods of ovulation stimulation in outcome of poor responders in ART
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Individuals with poor ovarian response in the ovulation stimulation cycle are characterized by the POSEIDON criterion. Groups 3 and 4 are entered.The third group of patients are under 35 years with abnormal ovarian reserve test AFC (number of antral follicles) less than 5 and antimullerian hormone less than 1.2 ng / cc. The fourth group of patients are over 35 years with abnormal ovarian reserve test AFC less than 5 And antimullerian hormone less than 1.2 ng / cc
Exclusion criteria:
Patients who are infected with the coronavirus during the cycle, patients who do not respond well to the ovulation stimulation cycle and do not actually have a follicle to empty, patients who received drug incorrectly during the cycle.
Age
From **30 years** old to **43 years** old
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **150**
Randomization (investigator's opinion)
Randomized
Randomization description
To start the ART cycle, patients are randomly divided into three groups. Due to the small sample size and to ensure the balance of the number of people in each group, we will use the restricted randomization method of block randomization and thus 15 out of 15 blocks including 2 Up to A, 2 to B and 2 to C will be formed.
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients who are eligible to enter the study are placed in one of three drug classes without the patient knowing, the results of the study after IVF are confidentially provided to a statistician for analysis
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Isfahan University of Medical Sciences
Street address
Isfahan University of Medical Sciences, Hezar jarib Ave., Isfahan
City
Isfahan
Province
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Postal code
73461-81746
Approval date
2022-04-25, 1401/02/05
Ethics committee reference number
IR.MUI.MED.REC.1401.032

Health conditions studied

1

Description of health condition studied
Infertility
ICD-10 code
N97
ICD-10 code description
Female infertility

Primary outcomes

1

Description
Comparison of the average number of oocytes obtained and the rate of chemical pregnancy, frequency of IMPLANTATION, frequency of CILINICAL PREGNANCY, frequency of ONGOING PREGNANCY is studied in three groups.
Timepoint
The time of oocyte count: after ovuum pickup, the time of positive pregnancy test: 2 weeks after embryo transfer, the time of pregnancy sac: 4 weeks after embryo transfer and the time of ongoing pregnancy rate:

in 12 weeks of pregnancy

Method of measurement

Evaluation of oocyte count after ovum pickup under a microscope to evaluate pregnancy test with HCG beta titration blood test and examination of pregnancy and pregnancy sac at 12 weeks with ultrasound

Secondary outcomes

1

Description

Nothing

Timepoint

Nothing

Method of measurement

Nothing

Intervention groups

1

Description

Intervention group: In the control group, the traditional ovulation stimulation method is given. In the first intervention group, the low-dose gonadotropin method is given

Category

Treatment - Drugs

2

Description

Intervention group: In the second group, the combined agonist and antagonist method is given.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan shahid beheshti hospital

Full name of responsible person

Ferdows Mehraian

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Sponsors / Funding sources

1

Sponsor

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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

Ferdows mehrabian

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

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Position
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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