

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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

Name

Hatav Ghasemi Tehrani

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 913 113 4081

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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

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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 CLINICAL PREGNANCY, frequency of ONGOING PREGNANCY is studied in three groups.

Timepoint

The time of oocyte count: after ovum 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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Isfahan University of Medical Sciences, Hezar jarib Ave., Isfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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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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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