Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 2026

Evaluation and comparison of GnRH antagonist versus long GnRH agonist protocol in poor responders undergoing IVF from POSEIDON group3- 4: A randomized clinical trial

Protocol summary

Study aim

comparison of GnRH antagonist versus long GnRH agonist protocol in poor responders undergoing IVF

Design

The phase 3 clinical trial, with a control group, will be conducted in parallel on 170 patients. The randomization of the samples will be done with Weber's simple randomization method according to the generated list of random numbers. The list of random numbers will be generated using the Random Allocation 1 software by A statistical consultant will be produced.

Settings and conduct

This study is conducted by the clinical trial method in Yazd Research Institute of Reproductive Sciences. The studied and control cases will be selected from among the people with poor ovarian response referring to the infertility clinic who are candidates for assisted reproductive methods. People who meet the inclusion criteria will be randomly assigned to two Gnrh agonist and Gnrh antagonist groups in the cycle of controlled ovarian stimulation.

Participants/Inclusion and exclusion criteria

Women aged 18 to 42 with poor ovarian response are candidates for ART without severe endometriosis and severe male factor infertility.

Intervention groups

Both groups of weakly responding patients who are candidates for ART will be selected. On the second day of the menstrual cycle, ultrasound will be performed and rFSH gonadotropin will be injected daily. In the agonist group, they will receive a depot dose of GnRH intramuscularly from the 21st day of the cycle before ovarian stimulation. . In the antagonist group, if there is a dominant follicle of 14 mm, steroid will be prescribed daily and will continue until the day of the trigger.

Main outcome variables

, the number of oocytes obtained, the number of embryos obtained with the qualities of A, B, C, the dose of gonadotropin used, the length of the ovarian stimulation period، clinical pregnancy

General information

Reason for update

Termination of the test and completion of information

Acronym

IRCT registration information

IRCT registration number: **IRCT20110509006420N28**
Registration date: **2024-01-30, 1402/11/10**
Registration timing: **prospective**

Last update: **2024-12-19, 1403/09/29**
Update count: **2**

Registration date

2024-01-30, 1402/11/10

Registrant information

Name

Maryam Eftekhar

Name of organization / entity

Yazd Research and Clinical Center for Infertility

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-30, 1402/11/10

Expected recruitment end date

2024-08-22, 1403/06/01

Actual recruitment start date
2024-01-31, 1402/11/11
Actual recruitment end date
2024-07-22, 1403/05/01
Trial completion date
2024-10-31, 1403/08/10

Scientific title
Evaluation and comparison of GnRH antagonist versus long GnRH agonist protocol in poor responders undergoing IVF from POSEIDON group3- 4: A randomized clinical trial

Public title
Evaluation of GnRH long-acting agonist protocols and GnRH antagonist protocol in controlled ovarian stimulation in in vitro fertilization in infertile women with poor ovarian response
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
IVF/ICSI candidates Women who respond poorly to ovulation stimulation: ovarian reserve less than 1.2 ng/ml and AFC number less than 5 POSEIDON group 3-4 Women between the ages of 18 and 42
Exclusion criteria:
sever Asherman's history Severe uterine adenomyosis Egg donation cycles Cases of severe male infertility (azoospermia) Cases where surrogacy is used Endocrine or metabolic diseases (hypothyroidism, hyperthyroidism)
Age
From **18 years** old to **42 years** old
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **170**
Actual sample size reached: **170**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, using the simple randomization method using the Random Allocation1 software (http://random-allocation software.informer.com\1) and based on the simple randomization method, the list of samples in the two groups studied by the expert Statistics will be generated. In this software, in order to generate a list of random numbers, first specify the number of groups to be studied as 2 and the total number of samples required as 170 people, and then from the list of sample randomization methods, the method (simple randomization method in parallel group) by considering the same number of samples in the groups. Then a random list will be generated based on the groups and the number of samples in each group. Randomly and after obtaining informed consent by the researcher, they are assigned to two groups. The sealed envelope method is used for concealment. The envelopes are prepared as many samples as each envelope contains the name of the intervention group for each sample. Is.
Blinding (investigator's opinion)
Not 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 Yazd reproductive Sience Institute- Shahid Sadoghi University of Medical Science
Street address
Yazd Reproductive Sciences Institute, BouAl Ave,Safaeih، Yazd, Yazd Province Yazd
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Approval date
2024-01-10, 1402/10/20
Ethics committee reference number
IR.SSU.RSI.REC.1402.019

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
4 weeks after embryo transfer
Method of measurement
sonography

Secondary outcomes

1

Description
rate of early abortion
Timepoint
the loss of the gestational sac or fetal heartbeat in clinically pregnant individuals prior to 8 weeks of gestational age
Method of measurement
sonography

2

Description
نرخ حاملگی مداوم
Timepoint
the continuation of pregnancy after 12 wk of gestational age.
Method of measurement
sonography

3

Description
Chemical pregnancy
Timepoint
2 weeks after embryo transfer
Method of measurement
pregnancy test

4

Description
Implantation
Timepoint
After a positive pregnancy test
Method of measurement
sonography

Intervention groups

1

Description
The GnRH antagonist group will start from the second day of the menstrual cycle, the ultrasound of gonadotropin IU225-300 rFSH signal-F daily subcutaneous injection. Then, if there is a dominant follicle ≥ 14 mm, the GNRH antagonist (Cetrotide 0.25 mg) is prescribed and will continue until the ovulation trigger day. With ultrasound monitoring, when there are The average follicle is ≥17 mm or one follicle is 18 mm, 10,000 hCG units were injected to induce the final maturation of follicles on the same day. Endometrial thickness and serum E2 level were measured for all 34-36 hours after the trigger under general anesthesia and ovarian puncture will be performed by ultrasound. became. 72 hours after ovarian puncture, two three-day-old embryos will be transferred and the remaining embryos will be frozen. If there is serum progesterone level ≥ 1.5ng/ml, all embryos will be frozen.
Category
Treatment - Drugs

2

Description
Intervention group: In the GnRH agonist long protocol group, they received a zoladex 3.6 mg dose of GnRH depot analog sc from day 21 of the cycle before ovarian stimulation. From the second day of the menstrual cycle, the ultrasound of gonadotropin IU225-300 rFSH signal-F will be injected daily subcutaneously. The dose of the drug will be adjusted according to the response of the ovary and will continue until the ovulation trigger day. With ultrasound monitoring, whenThe average follicle is ≥17 mm or one follicle is 18 mm In order to induce the final maturation of the follicle, 10,000 units of HCG were injected on the same day. Endometrial thickness and E2 serum level were measured for all 34-36 hours after the trigger under general anesthesia and ovarian puncture will be performed under ultrasound guidance. 72 hours after ovarian puncture, two three-day-old embryos will be transferred and the remaining embryos will be frozen. If there is serum progesterone level ≥ 1.5ng/ml, all embryos will be frozen.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Yazd Reproductive Sciences Institute
Full name of responsible person
Zahra Amini Majomerd
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Amin Salehi Abargouei
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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
Yazd 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
Yazd University of Medical Sciences

Full name of responsible person
maryam eftekhar

Position
professor

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
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Position
professor

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

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Person responsible for updating data

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Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is 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

Title and more details about the data/document

All participant data sets are to be shared

When the data will become available and for how long

2 months after the result publication

To whom data/document is available

In order to receive data or other study documents, researchers working in academic and scientific institutions are allowed to apply

Under which criteria data/document could be used

To evaluate the accuracy of the data and use data to complete other researches

From where data/document is obtainable

Yazd Reproductive Sciences Institute, Bouali Ave, Yazd, Iran

What processes are involved for a request to access data/document

Request from the Research Deputy, submitted to the Research Council of the Center if the request accepts its referral to the security and after completion of the relevant forms, the request is referred to the research experts and then get the data.

Comments