Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Sep 2026

Comparison of the Effect of the early initiation of GnRH Antagonist in the Early Follicular Phase in Poor Responder Patients

Protocol summary

Study aim
Comparison of the Effect of the early initiation of GnRH Antagonist in the Early Follicular Phase in Poor Responder Patients

Design
This study was designed as a single-blinded randomized clinical trial with parallel groups and a sample size of 58 people in each group.

Settings and conduct
The study will be conducted at Arash Women's Hospital on all women undergoing IVF. Patients who signed informed consent will be randomly divided into two groups. The first group will receive the Early protocol, including Recombinant FSH with LH and antagonist started simultaneously on day 2 of the cycle. The second group will receive the Conventional antagonist protocol, which included Recombinant FSH with LH starting on day 2 of the cycle and injection of antagonist when the follicles sizes reach 14-13 mm. In both groups, the final oocyte maturation will be triggered by of HCG injection when at least one 18-mm and two 16-mm follicles were detected on ultrasound. The ovarian puncture will be performed 36 hours after HCG injection. One or two embryos will be transferred, three days after the puncture. The luteal phase support will be performed with 400 mg of Progesterone suppository. The final outcome of the study will be assessed by a third party who is unaware of the study process. Also, the statistician will be unaware of the study process.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Bologna criteria (described in the relevant section) Exclusion criteria: Polycystic ovary syndrome, hypothalamic amenorrhea, congenital uterine anomaly, and uterine cavity problems, chronic diseases, more than three times consecutive IVF failure

Intervention groups
Group One: The Early Antagonist Protocol Group Two: The Conventional Antagonist Protocol

Main outcome variables
Total number of mature oocytes; Total number of embryos

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110731007165N9**
Registration date: **2020-02-08, 1398/11/19**
Registration timing: **registered_while_recruiting**

Last update: **2020-02-08, 1398/11/19**
Update count: **0**

Registration date
2020-02-08, 1398/11/19

Registrant information

Name
Ladan Kashani

Name of organization / entity
Tehran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-10-06, 1398/07/14

Expected recruitment end date
2020-03-19, 1398/12/29

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effect of the early initiation of GnRH Antagonist in the Early Follicular Phase in Poor Responder Patients

Public title

Early initiation of GnRH Antagonist in Poor responder Patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18 up to 44 years History of poor ovarian response (POR) in previous cycle (oocyte less than 3 in a conventional protocol) Antral follicle count (AFC) less than 5-7 or Anti-Müllerian hormone (AMH) <0.5-1.1 Poor ovarian response after maximal stimulation

Exclusion criteria:

Polycystic Ovarian Syndrome Hypothalamic amenorrhea Uterine congenital anomalies and uterine cavity abnormalities (Bicorn uterus, Unicorn uterus, Asherman, Liomyuma, Polyp, etc.) Repeated IVF failure (more than three consecutive failures)

Age

From **18 years** old to **44 years** old

Gender

Female

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size

Target sample size: **116**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization list will be prepared by the statistician. Treatments will be placed in sealed envelopes and will be kept by the out-of-study nurse. After identification of the eligibility of the patient, the procedure will be explained to her and informed consent will be obtained.

Blinding (investigator's opinion)

Single blinded

Blinding description

Completion of the final information is up to the person who is unaware of the type of treatment and also the specialist will be blind.

Placebo

Not used

Assignment

Parallel

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

Qods St, Keshavarz Blvd, Tehran, Iran

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1417653761

Approval date

2019-10-05, 1398/07/13

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1398.544

Health conditions studied

1

Description of health condition studied

Poor Ovarian Response

ICD-10 code

N98

ICD-10 code description

Complications associated with artificial fertilization

Primary outcomes

1

Description

Number of Mature Retrieved Oocytes

Timepoint

At the end of the study

Method of measurement

Embryology Report

2

Description

Embryos

Timepoint

At the end of the study

Method of measurement

Embryology Report

3

Description

Total Gonadotropins used

Timepoint

At the end of the study

Method of measurement
Checklist

4

Description
Total Antagonist used
Timepoint
At the end of the study
Method of measurement
Checklist

5

Description
Total Days of Induction of ovulation
Timepoint
At the end of the study
Method of measurement
Checklist

6

Description
Total Number of Retrieved Oocytes
Timepoint
At the end of the study
Method of measurement
Embryology Report

Secondary outcomes

1

Description
Clinical Pregnancy
Timepoint
At the end of the study
Method of measurement
Pregnancy confirmed by both high levels of hCG and presence of gestational sac with positive heart beats in ultrasound

2

Description
Ongoing pregnancy
Timepoint
At the end of the study
Method of measurement
Pregnancy had continued more than 12 weeks of gestation

3

Description
Chemical Pregnancy
Timepoint
At the end of the study
Method of measurement
A very early pregnancy loss in the first few weeks

4

Description
Luteinizing Hormone (LH) Level
Timepoint
In the second day of the cycle and then one time in trigger day
Method of measurement
Blood Test

5

Description
Progestrone Level
Timepoint
In the second day of the cycle and then one time in trigger day
Method of measurement
Blood Test

6

Description
Estradiol Level
Timepoint
In the second day of the cycle and then one time in trigger day
Method of measurement
Blood Test

7

Description
Implantation Rate
Timepoint
At the end of the study
Method of measurement
The percentage of embryos which successfully undergo implantation compared to the number of embryos transferred in a given period.

8

Description
Fertilization rate
Timepoint
At the end of the study
Method of measurement
Percentage of transformation of micro injected oocytes into two pronuclei

Intervention groups

1

Description
Intervention group: Early antagonist protocol: Recombinant FSH (150-225 IU) and GnRH Antagonist (Cetrotid 0.25 mg) will be started simultaneously on the second day of the cycle. Final oocyte maturation will be triggered with 5000 units of HCG when at least one 18-mm and two 16-mm follicles were detected on ultrasound. The ovarian puncture will be performed 36

hours after HCG injection. One or two embryos will be transferred three days after the ovarian puncture. The luteal phase support will be performed by the use of 100 mg of Progesterone.

Category

Treatment - Drugs

2

Description

Control group: Conventional antagonist protocol: Recombinant FSH (150-225 IU) will be started on day 2 of the cycle and the Antagonist (Cetrotid 0.25 mg) will be injected when follicle size reaches to 13-14 mmHg. Final oocyte maturation will be triggered with 5000 units of HCG when at least one 18-mm and two 16-mm follicles were detected on ultrasound. The ovarian puncture will be performed 36 hours after HCG injection. One or two embryos will be transferred three days after the ovarian puncture. The luteal phase support will be performed by the use of 100 mg of Progesterone.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Arash women's hospital

Full name of responsible person

Dr.Ladan Kashani

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Sponsors / Funding sources

1

Sponsor

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Dr. Tayebeh Esfidani

Position

Fellowship

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

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Name of organization / entity
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Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Gynecology and Obstetrics

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Person responsible for updating data

Contact

Name of organization / entity
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Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Gynecology and Obstetrics

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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
Not applicable

Data Dictionary
Not applicable