

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

08 Jul 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8828 1866

##### Email address

kashani\_ladan@tums.ac.ir

##### 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, Liomyoma, 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

##### City

Tehran

##### Province

Tehran

##### Postal code

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

Progesterone 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

**Street address**

No. 162 Alley (Abdul Majid), Shahid Baghdarnia Street (North Rashid), Shahid Bagheri Highway, Resalat Highway, Tehran, Iran

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**Web page address**

<http://arash.tums.ac.ir/>

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr Mohammad Ali Sahraian

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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. Tayebbeh Esfidani

**Position**

Fellowship

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Gynecology and Obstetrics

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Ladan Kashani

**Position**

Associate professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

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## Person responsible for updating data

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Dr. Ladan Kashani

**Position**

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**Latest degree**

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**Other areas of specialty/work**

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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