

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### Comparison of the effect of delayed start GnRH antagonist protocol and usual antagonist protocol on oocyte count and pregnancy rate in ART cycle in poor ovarian responders

#### Protocol summary

##### Study aim

Effect of delayed start GnRH protocol in ovarian poor responders

##### Design

Interventional clinical trial with control and parallel groups, non-blind, randomized, phase 2 was performed on 72 patients. Randomization was performed using random number table.

##### Settings and conduct

The objective of this study is evaluating the effect of delayed start protocol in ovarian poor responders. Study population: Infertile women with poor ovarian response candidate for IVF. Study groups: Intervention and control groups. Sample size: 72 poor responder women. This is a randomized not blinded trial, in one center, in phase 2 study. Setting and conduct: Ovarian poor responders after obtaining informed consent randomized into intervention and control groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patient with Bologna criteria for ovarian poor responders Exclusion criteria: History of endocrine disorders, severe endometriosis, azoospermia.

##### Intervention groups

In the intervention group with delayed protocol: First, like the control group, estradiol valerate 4 mg daily for 10 days starts from the 20th day of the previous menstrual cycle, then 7 days of daily administration of gonadotropin-releasing hormone antagonist (0.25 mg cetorelix acetate) begins. The ovaries are then stimulated with 375 u gonadotropins. In the control group ovarian stimulation was performed using standard GnRH protocol with 375u gonadotropin.

##### Main outcome variables

Number of mature oocytes (MII) and total number of oocytes

#### General information

##### Reason for update

Updating the trial according to the last changes in Actual sample size reached and secondary outcomes

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2015100424335N1**

Registration date: **2016-01-18, 1394/10/28**

Registration timing: **retrospective**

Last update: **2021-08-10, 1400/05/19**

Update count: **3**

##### Registration date

2016-01-18, 1394/10/28

##### Registrant information

##### Name

robabe hoseinisadat

##### Name of organization / entity

infertility institute center of shahid sadoughi

##### Country

Iran (Islamic Republic of)

##### Phone

+98 35 3824 7085

##### Email address

robabehoseini@ssu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Shahid Sadoughi University of Medical Sciences

##### Expected recruitment start date

2015-03-01, 1393/12/10

##### Expected recruitment end date

2015-09-30, 1394/07/08

##### Actual recruitment start date

2015-03-01, 1393/12/10

**Actual recruitment end date**

2015-09-30, 1394/07/08

**Trial completion date**

2016-03-30, 1395/01/11

**Scientific title**

Comparison of the effect of delayed start GnRH antagonist protocol and usual antagonist protocol on oocyte count and pregnancy rate in ART cycle in poor ovarian responders

**Public title**

Effect of delayed start protocol in outcome of ART cycle in poor ovarian responders

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Poor ovarian responders according to Bologna criteria. At least two of the following three features must be present: Advanced maternal age ( $\geq 40$  years) or any other risk factor for poor ovarian response; A previous poor ovarian response ( $\leq 3$  oocytes with a conventional stimulation protocol); An abnormal ovarian reserve test (i.e. AFC  $< 5-7$  follicles or AMH  $< 1.1$  ng/ml). Two episodes of POR after maximal stimulation are sufficient to define a patient as poor responder.

**Exclusion criteria:**

History of endocrine and metabolic disorders  
endometriosis azoospermia

**Age**

From **18 years** old to **45 years** old

**Gender**

Female

**Phase**

2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **72**

Actual sample size reached: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this trial, 72 infertile women with poor ovarian response were informed about the research design and signed a written consent form. All women were randomly divided into two groups. Randomization was simple, individual, not blinded, using a random number table.

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features**

Randomized with enveloped pocket method

**Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Shahid Sadoughi University of Medical Sciences

**Street address**

Research and Clinical Center for Infertility, Bouali, Timsar Fallahy, Safayeh, Yazd

**City**

Yazd

**Province**

Yazd

**Postal code**

8916877391

**Approval date**

2015-06-07, 1394/03/17

**Ethics committee reference number**

148

**Health conditions studied****1****Description of health condition studied**

Infertility

**ICD-10 code**

N98.9

**ICD-10 code description**

Complication associated with artificial fertilization, unspecified

**Primary outcomes****1****Description**

Mature oocytes count

**Timepoint**

Oocyte retrieval day

**Method of measurement**

Counting number of mature oocytes with microscope

**2****Description**

Total oocytes count

**Timepoint**

Oocyte retrieval day

**Method of measurement**

Counting number of total oocytes with microscope

**Secondary outcomes****1****Description**

Number of embryo

**Timepoint**

On the 2nd day after ICSI  
**Method of measurement**  
Observation with microscope

## 2

**Description**  
Chemical pregnancy  
**Timepoint**  
14 days after embryo transfer  
**Method of measurement**  
Serum  $\beta$ hCG

## 3

**Description**  
Clinical pregnancy  
**Timepoint**  
3 weeks after positive serum  $\beta$ hCG  
**Method of measurement**  
Vaginal ultrasonography

## 4

**Description**  
oocyte maturity rate (MII number /total oocytes number)  
**Timepoint**  
oocyte retrieval day  
**Method of measurement**  
with microscope

## 5

**Description**  
oocyte yield (total oocytes number /antral follicle count [AFC])  
**Timepoint**  
oocyte retrieval day for oocyte count and before the start of the ivf cycle for antral follicles  
**Method of measurement**  
With microscope for oocytes and vaginal ultrasound for antral follicles

## 6

**Description**  
mature oocyte yield (MII number/AFC)  
**Timepoint**  
oocyte retrieval day for mature oocyte count and before the start of the ivf cycle for antral follicles  
**Method of measurement**  
With microscope for mature oocytes and vaginal ultrasound for antral follicles

## 7

**Description**  
total dosage of gonadotropin  
**Timepoint**  
End of IVF cycle  
**Method of measurement**  
Count the dose of gonadotropin received

## 8

**Description**  
ovarian stimulation days  
**Timepoint**  
End of IVF cycle  
**Method of measurement**  
Counting the days of ovarian stimulation

## 9

**Description**  
fertilization rate (two-pronuclear [2PN]/ MII)  
**Timepoint**  
16 hr after Intra-cytoplasmic sperm injection  
**Method of measurement**  
With microscope

## 10

**Description**  
Implantation rate (the number of gestational sacs divided/the number of transferred embryos)  
**Timepoint**  
3 week after positive serum  $\beta$ hCG  
**Method of measurement**  
Vaginal ultrasonography

## 11

**Description**  
Ongoing pregnancy rate  
**Timepoint**  
after 12 week gestation  
**Method of measurement**  
ultrasound

## 12

**Description**  
miscarriage rate  
**Timepoint**  
miscarriages before 20 weeks gestation  
**Method of measurement**  
ultrasound

## **Intervention groups**

### 1

**Description**  
In intervention group 0/25 mg/vial cetrorelix( GNRH antagonist), one vial daily, subcutaneous, for 7 days, before starting COH. Then start ovarian stimulation with 375 units of gonadotropin  
**Category**  
Treatment - Drugs

### 2

**Description**  
in control group patients treated with antagonist protocol with 375 units of gonadotropin, without GNRH antagonist

pretreatment.

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Research and Clinical Center for Infertility, Shahid Sadoughi University of Medical Sciences

**Full name of responsible person**

Robabe Hosseinisadat

**Street address**

Research and Clinical Center for Infertility, Bouali, Timsar Fallahy, Safayeh, Yazd

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**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Vice Chancellor for research of Shahid Sadoughi University of Medical Sciences

**Full name of responsible person**

Masoud Mirzaei

**Street address**

Bahonar Square, Yazd

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**Province**

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dvc.research@ssu.ac.ir

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice Chancellor for research of Shahid Sadoughi 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**

Kerman University of Medical Sciences

**Full name of responsible person**

Robabe Hosseinisadat

**Position**

Assistant Professor

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

Imam Khomeini Highway, Afzalipour Infertility center

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**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

Professor

**Latest degree**

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**Other areas of specialty/work**

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**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Robabe Hosseinisadat

**Position**

Assistant Professor

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

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**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

The final result of the study will be published and there is no need to share individual participants' data

**Study Protocol**

Yes - There is a plan to make this available

**Statistical Analysis Plan**

Yes - There is a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

**Title and more details about the data/document**

The final result of the study will be published and there is no need to share individual participants' data

**When the data will become available and for how long**

The final result of the study will be published and there is no need to share individual participants' data

**To whom data/document is available**

The final result of the study will be published and there is no need to share individual participants' data

**Under which criteria data/document could be used**

The final result of the study will be published and there is no need to share individual participants' data

**From where data/document is obtainable**

The final result of the study will be published and there is no need to share individual participants' data

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

The final result of the study will be published and there is no need to share individual participants' data

**Comments**