

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 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

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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 (≥ 40 years) or any other risk factor for poor ovarian response; A previous poor ovarian response (≤ 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

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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 β hCG

3

Description
Clinical pregnancy
Timepoint
3 weeks after positive serum β 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 β 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

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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

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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

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

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Other areas of specialty/work

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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