

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### The Comparison of the GnRH Agonist-Antagonist Protocol (AAP) with GnRH Antagonist Protocol in Women with Poor Ovarian Response in Assisted Reproduction Technique (ART) during Controlled Ovarian Hyper Stimulation Cycles

#### Protocol summary

##### Study aim

The Comparison of the GnRH Agonist-Antagonist Protocol (AAP) with GnRH Antagonist Protocol in Women with Poor Ovarian Response in Assisted Reproduction Technique (ART) during Controlled Ovarian Hyper Stimulation Cycles

##### Design

In this double-blinded randomized controlled clinical trial, 80 infertile female patients will be randomly divided into two groups of 40 cases.

##### Settings and conduct

This study will be performed in infertility department of Zeinab Educational Center of Shiraz. The intervention group receive gonadotropin (225 units of gonadal F and 3 HMG ampoules) on the second day of menstruation, and each time the follicle reaches a size of 13-14 mm, the GnRH antagonist (Cetrotide, 0.25 mg SQ) is injected and continued with gonadotropins until the follicle reaches a size of 17-18 mm and finally artificial insemination will take place. In the control group, after gonadotropin and HMG injection, treatment with GnRH antagonist was continued without gonadotropins. Patients and clinical researchers will not be informed about the distribution of the drugs between two groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients aged between 18 and 42 years who fulfill the Bologna criteria; lack of endometriosis stage 3 and 4; and no specimen of TESE (Testicular Sperm Extraction). Exclusion criteria: Presence of the specimen of TESE (Testicular Sperm Extraction); endometriosis stage 3 and 4.

##### Intervention groups

Infertile women candidates for using the assisted reproduction technique (ART) will be randomly divided into two groups of intervention and control: 1- Intervention group: Eligible infertile women (according to

Bologna criteria) who are treated with GnRH agonist-antagonist protocol. 2- Control group: Eligible infertile women (according to Bologna criteria) who are treated with GnRH antagonist protocol.

##### Main outcome variables

Successful implantation rate

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120708010210N9**

Registration date: **2020-04-10, 1399/01/22**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-04-10, 1399/01/22**

Update count: **0**

##### Registration date

2020-04-10, 1399/01/22

##### Registrant information

##### Name

Afsun Zarei

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 1233 2365

##### Email address

zareia@sums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

**Expected recruitment start date**

2019-04-14, 1398/01/25

**Expected recruitment end date**

2020-05-20, 1399/02/31

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The Comparison of the GnRH Agonist-Antagonist Protocol (AAP) with GnRH Antagonist Protocol in Women with Poor Ovarian Response in Assisted Reproduction Technique (ART) during Controlled Ovarian Hyper Stimulation Cycles

**Public title**

The Comparison of Two Protocols for Treatment of Infertility

**Purpose**

Treatment

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

Age between 18 and 42 years All patients fulfill the Bologna criteria

**Exclusion criteria:**

Presence of the specimen of TESE (Testicular Sperm Extraction) Endometriosis stage 3 and 4

**Age**

From **18 years** old to **42 years** old

**Gender**

Female

**Phase**

2

**Groups that have been masked**

- Participant
- Investigator

**Sample size**

Target sample size: **80**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization is performed using the block method and Random Allocation Software version 2 will be used in the preparation of 4-case blocks. The drugs in both groups are packaged and numbered in similar vials apparently by a researcher who is not involved in patient selection and follow-up.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The clinical investigators (in direct contact with the patient), and participants will not be aware of the distribution of the drugs in the groups (double blinded), so that they are unaware of the content and dosage of the prescribed medication, and the medications will be similar in appearance.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics committee of Shiraz University of Medical Sciences

**Street address**

Faculty of medicine, Zand Avenue

**City**

Shiraz

**Province**

Fars

**Postal code**

71937-11351

**Approval date**

2019-12-15, 1398/09/24

**Ethics committee reference number**

IR.SUMS.MED.REC.1398.516

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

Female infertility

**ICD-10 code**

N97

**ICD-10 code description**

Female infertility

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

Clinical pregnancy rate

**Timepoint**

Two months after embryo transfer

**Method of measurement**

Vaginal sonography

**2****Description**

Chemical pregnancy rate

**Timepoint**

Fourteen days after embryo transfer

**Method of measurement**

Pregnancy Test

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: GnRH antagonist (Cetrotide, 0.25 mg SQ) with gonadotropin (225 units of gonadal F and 3 HMG ampoules) until artificial insemination

#### Category

Treatment - Drugs

### 2

#### Description

Control group: GnRH antagonist (Cetrotide, 0.25 mg SQ) and continuing treatment without gonadotropin until artificial insemination

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Hazrate Zeinab Hospital

##### Full name of responsible person

Parisa Keshtkaran

##### Street address

Sibooyeh blvd

##### City

Shiraz

##### Province

Fars

##### Postal code

71538-13311

##### Phone

+98 71 3726 6811

##### Email

zeinabhp@sums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Younes Ghasemi

##### Street address

Vice chancellor of research, 7th floor of central building of Shiraz University of Medical Sciences, Zand Ave.

##### City

Shiraz

##### Province

Fars

##### Postal code

71348-14336

##### Phone

+98 71 3235 7282

##### Fax

+98 71 3235 7282

##### Email

ghasemiy@sums.ac.ir

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

##### Full name of responsible person

Parisa Keshtkaran

##### Position

Resident

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Gynecology and Obstetrics

##### Street address

Hazrat Zeinab Hospital, Sibuyeh blvd.

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parisa\_18\_k@yahoo.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Shiraz University of Medical Sciences

**Full name of responsible person**

Afsoon Zarei

**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)**

Yes - There is a plan to make this available

**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**

Yes - There is a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

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

Information about main outcomes of the study

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

Six months after publishing the results

**To whom data/document is available**

Researchers in universities and scientific and research centers

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

In order to improve the treatment of infertility and subsequent researches and with the permission of the authors

**From where data/document is obtainable**

Department of Obstetrics and Gynecology of Shiraz university of medical sciences

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

Sending the request in writing or by email to the authors

**Comments****Person responsible for updating data****Contact****Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Parisa Kestkaran

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Gynecology and Obstetrics

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