

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

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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.

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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

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Afsoon Zarei

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Associate professor

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Subspecialist

Other areas of specialty/work

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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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