

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 2026

Clinical trial comparing IVF results in two GnRH antagonist protocols and Stop protocol (GnRH agonist/antagonist) in patients with polycystic ovary syndrome

Protocol summary

Study aim

Comparison of IVF outcomes in two conventional protocols (antagonist) and Stop GnRH agonist/GnRH antagonist in PCO patients

Design

The clinical trial has a control group, with parallel groups, without blinding, randomized, on 60 patients. The random allocation method was a block using WWW.Sealedenvelop.com. The blocks will be 2 alleles of size 6.

Settings and conduct

Valiasr Hospital Patients are entered into two groups with two different ovulation stimulation regimens and oocyte puncture is performed

Participants/Inclusion and exclusion criteria

Age 20 to 35 years; PCO criteria based on Rotterdam criteria; Sperm analysis is normal or has the minimum necessary criteria for ICSI; AMH above 5; At least one year of infertility

Intervention groups

In the GnRH regimen, Stop starts in the mid-luteal phase (previous cycle) and stops with the onset of menstruation. Then the gonadotropin cycle starts on days 2-3. In both groups, after 5 days, subcutaneous antagonist injection is performed for two days. But in the usual antagonist regimen, gonadotropins start on days 2-3 of the menstrual cycle with a dose of 150-225 units subcutaneously. The patient takes gonadotropin for at least 5 days, and from the 6th day of gonadotropin use, in both vaginal ultrasound groups, folliculography is performed every 2 or 3 days. When the leading follicle reaches the size of 13-14 mm, the antagonist is started. From now on, in both regimes, when at least 2-3 follicles above 18 are observed, the final trigger is done with GnRH agonist, and 34-40 hours later, the puncture is done.

Main outcome variables

The number of follicles above 16 mm, the degree of SYNCHRONY of follicles, the number and quality of oocytes, the number and quality of embryos

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180409039247N8**

Registration date: **2023-08-17, 1402/05/26**

Registration timing: **prospective**

Last update: **2023-08-17, 1402/05/26**

Update count: **0**

Registration date

2023-08-17, 1402/05/26

Registrant information

Name

Marjan Ghaemibidgoli

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8800 4858

Email address

m_ghaemi@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-23, 1402/06/01

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial comparing IVF results in two GnRH antagonist protocols and Stop protocol (GnRH agonist/antagonist) in patients with polycystic ovary syndrome

Public title

comparing IVF results in two GnRH antagonist protocols and Stop protocol (GnRH agonist/antagonist) in patients with polycystic ovary syndrome

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

PCO patients according to Rotterdam criteria Age 20 to 35 years Infertility > 1 year Sperm analysis is normal or has the minimum necessary criteria for ICSI AMH above 5

Exclusion criteria:

History of autoimmune diseases, coagulation disorders, uterine anomalies, chromosomal and genetic disorders, chronic renal and metabolic diseases, hypo and hyperthyroidism, history of malignancy, endometriosis, history of repeated miscarriage and repeated implantation failure Pharmaceutical reaction to ovulation stimulation drugs Lack of follicle growth suitable for puncture The patient's lack of consent to complete the treatment course Severe Oligoastenoteratospermia

Age

From **20 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants will be randomly assigned to one of two groups. A computerized randomization list, generated by an independent statistician blinded to the trial, will use 1:1 allocation. The block random allocation method was designed by an epidemiologist using WWW.Sealedenvelop.com. The blocks will be 2 alleles of size 6. AAABBB-AABBAB-ABBBAA-AABABB-....., in this sequence A and B that only the main researcher knows its meaning.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Tehran university of Medical sciences

Street address

East Bagherkhan Street

City

Tehran

Province

Tehran

Postal code

14146

Approval date

2023-07-19, 1402/04/28

Ethics committee reference number

IR.TUMS.IKHC.REC.1402.169

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

infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

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

The number of follicles above 16 mm, the degree of follicle synchrony, the number and quality of obtained oocytes (metaphase 1, 2 and GV)

Timepoint

The examination will be cross-sectional on the day of oocyte puncture.

Method of measurement

Questionnaire for demographic information and patient records, ultrasound to check follicles and embryology laboratory information to check the number and quality of oocytes and embryos.

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

Number and quality of embryos

Timepoint

On the day of ovarian puncture

Method of measurement

It is determined by the embryologist three days after the

puncture.

Intervention groups

1

Description

Intervention group: In the GnRH group, Stop starts in the mid-luteal phase (previous cycle) and with the onset of menstruation on the 2nd-3rd day of the gonadotropin cycle, the dose of 150-225 units subcutaneously, depending on the patient's condition. The patient takes gonads for at least 5 days, and from the 6th day of taking gonadotropin, vaginal ultrasound and folliculography are performed every 2 or 3 days. When the leading follicle reaches the size of 13-14 mm, the antagonist is started, and when at least 2-3 follicles above 18 are observed, the final trigger is done with GNRH agonist, and 34-40 hours later, the puncture is done.

Category

Treatment - Drugs

2

Description

Control group: In this group, gonadotropins are started on day 2-3 of the menstrual cycle with a dose of 150-225 units subcutaneously, depending on the patient's condition. The patient takes gonads for at least 5 days, and from the 6th day of taking gonadotropin, vaginal ultrasound and folliculography are performed every 2 or 3 days. When the leading follicle reaches the size of 13-14 mm, the antagonist is started, and when at least 2-3 follicles above 18 are observed, the final trigger is performed with GNRH agonist, and 34-40 hours later, the puncture is performed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Vali-e-Asr hospital

Full name of responsible person

Marjan Ghaemi

Street address

East Bagherkhan Street

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 21 6116 2365

Email

marjan_ghaemi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi

Street address

Quds Steet. Intersection with Keshavarz Blvd

City

Tehran

Province

Tehran

Postal code

1417613151

Phone

+98 21 8163 0000

Email

info@tums.ac.ir

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

Marjan Ghaemi

Position

Assissted professor

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Emam khomeini hospital

City

Tehran

Province

Tehran

Postal code

14146

Phone

+98 21 8800 4858

Fax

Email

marjan_ghaemi@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Marjan Ghaemi

Position

Assisted professor

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Emam khomeini hospital

City

Tehran

Province

Tehran

Postal code

14146

Phone

+98 21 8800 4858

Fax

Email

marjan_ghaemi@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Marjan Ghaemi

Position

Assisted professor

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Emam khomeini hospital

City

Tehran

Province

Tehran

Postal code

14146

Phone

+98 21 8800 4858

Fax

Email

marjan_ghaemi@yahoo.com

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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available