# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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 follicography 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 follicography 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**

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 updating data

**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

## 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