

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Effect of simultaneous administration of FSH and hCG for triggering on oocyte quality and ART outcome in antagonist protocol

#### Protocol summary

##### Study aim

Determining the effect of simultaneous administration of FSH and hCG for triggering on oocyte quality and ART outcome in antagonist protocol

##### Design

A Randomized, single-blinded, controlled clinical trial with a parallel-group design of 110 patients. The randomization list was generated by using the "www.sealedenvelope.com" site.

##### Settings and conduct

Location: Infertility ward of Arash Women's Hospital  
Method: The patients enter the antagonist cycle and after frequent follicular monitoring and defining the triggering time, informed consent is obtained and the patient is randomized into two groups HCG 10000+FSH450I.U. or HCG 10000; both groups undergo oocyte pickup 34-36 hours after triggering. the oocytes will be denuded and evaluated by the embryologist, then IVF/ICSI is done and after 2 or 3-day embryos, if present will be transferred. Blinding: Single Blinded

##### Participants/Inclusion and exclusion criteria

Inclusion: age between 18-38; FSH below10 and AFC more than 5; normal uterine cavity; antagonist protocol IVF cycles  
Non Inclusion: Estradiol than 4500; Cancellation of oocyte retrieval; History of more than 2 failed IVF/ICSI; Severe male factor

##### Intervention groups

Intervention group: injection of 450 units of FSH plus1000 units of HCG  
Control group: injection of only 1000 units of HCG

##### Main outcome variables

Oocyte quality

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20150310021420N5**

Registration date: **2021-06-14, 1400/03/24**

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

Last update: **2021-06-14, 1400/03/24**

Update count: **0**

##### Registration date

2021-06-14, 1400/03/24

##### Registrant information

###### Name

Maryam Farid Mojtahedi

###### Name of organization / entity

Arash women hospital,clinic for infertility,Tehran university of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 7788 8755

###### Email address

m\_fmjtahedi@ssu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Tehran University of Medical sciences

##### Expected recruitment start date

2021-05-20, 1400/02/30

##### Expected recruitment end date

2021-09-22, 1400/06/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of simultaneous administration of FSH and hCG for triggering on oocyte quality and ART outcome in antagonist protocol

**Public title**

FSH administration for triggering final oocyte maturation in improving ART outcome

**Purpose**

Treatment

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

age between 18 and 38 third day FSH below 10 IU/ml and AFC more than 5 in each ovary normal uterine cavity antagonist protocol IVF cycles

**Exclusion criteria:**

Estradiol at day of trigger more than 4500 IU/l  
Cancellation of oocyte retrieval due to cycle cancellation or changing to IUI  
History of more than 2 failed IVF/ICSI  
Severe male factor

**Age**

From **18 years** old to **38 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **110**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

According to Stratified Block randomization, the samples will be divided into two groups of intervention and control. The number of blocks will be 6. The mentioned list will be generated by using the "www.sealedenvelope.com" site. The random allocation list is solely available to the epidemiologist. For the Concealment of the random allocation process, treatments will be written on 110 cards, respectively. then the cards are placed inside sealed envelopes. When the physician announces the eligibility of a patient, the methodologist will provide the physician with the envelope.

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

The assessor of the final outcome (oocyte quality), who is the embryologist, is unaware of the type of cycle regimen. The data analyzer is also unaware of the type of intervention.

**Placebo**

Used

**Assignment**

Parallel

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

empty

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

Ethics committee of School of Medicine - Tehran University of Medical Sciences

**Street address**

Poorsina st - Qods st - enghelab st - Tehran-Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1417653761

**Approval date**

2017-02-01, 1395/11/13

**Ethics committee reference number**

IR.TUMS.MEDICINE.REC.1395.1601

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

femaleInfertility

**ICD-10 code**

N97.9

**ICD-10 code description**

Female infertility, unspecified

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

Oocyte quality

**Timepoint**

Day of ovarian puncture

**Method of measurement**

gardner scale by microscope

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

clinical pregnancy

**Timepoint**

28 days after transfer

**Method of measurement**

vaginal ultrasound and observation of fetal heart beat

**2****Description**

ongoing pregnancy

**Timepoint**

after first trimester

**Method of measurement**

sonography and observation of alive fetus

## Intervention groups

### 1

#### Description

Intervention group: The patients enter antagonist cycle and after frequent follicular monitoring and defining the triggering time . When at least two oocytes were seen HCG 10000+FSH450I.U were injected.

#### Category

Treatment - Drugs

### 2

#### Description

Control Group: The patients enter antagonist cycle and after frequent follicular monitoring and defining the triggering time . When atleast two oocytes were seen, HCG 10000 was injected.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Arash women's hospital

##### Full name of responsible person

Maryam Farid Mojtahedi

##### Street address

Arash Women 's Hospital, Rashid Ave, Resalat Highway, Tehranparse

##### City

Tehran

##### Province

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##### Postal code

1653915981

##### Phone

+98 21 7788 3283

##### Email

m\_fmjtahedi@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Dr Mohammad Ali Sahraian

##### Street address

Qods St, Keshavarz Blv, Tehran, Iran

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##### Province

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##### Postal code

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#### Phone

+98 21 8163 3619

#### Fax

+98 21 8163 3611

#### Email

rmo@tums.ac.ir

#### Web page address

http://vcr.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

Maryam Faridmojtahedi

##### Position

Assistant Professor

##### Latest degree

Subspecialist

##### Other areas of specialty/work

Gynecology and Obstetrics

##### Street address

Arash Women's Hospital, Resalt highway, Tehranpars, Rashid Ave.

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1653915981

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Tehran University of Medical Sciences

**Full name of responsible person**

Maryam Faridmojtahedi

**Position**

Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

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**Fax****Email**

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**Web page address****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**All data set and study protocol potentially after  
nonidentification of patients can be shared.**When the data will become available and for how long**

6 months after publication of manuscript

**To whom data/document is available**

Academic and scientific researches

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

It is usable by mentioning the reference

**From where data/document is obtainable**

It should be requested by Email

m\_fmjtahedi@yahoo.com Dr.Maryam farid Mojtahedi

**What processes are involved for a request to access data/document**If it be requested by Email, it will be answered in one  
month**Comments****Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Maryam Faridmojtahedi

**Position**

Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Gynecology and Obstetrics

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Tehran

**Province**