

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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 below 10 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 plus 1000 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+FSH450IU 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

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1653915981

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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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+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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Web page address

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Contact

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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

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Latest degree

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Other areas of specialty/work

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