# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 2026

## Comparing the outcomes of dual trigger with GnRh agonist along with HCG versus HCG alone in normal responder patients in antagonist ART protocol

## Protocol summary

**Summary**

In a randomized clinical trial of patients referred to Avicenna Infertility Center, we will compare double trigger by GnRh agonist along with HCG versus HCG alone in improving the ART results. After considering the including criteria and receiving appropriate consents, patients are enrolled in the trial. The antagonist cycle begins as Flexible Step Up protocol. When at least two follicles larger than 17 or 18 mm are seen, patients will be divided into two groups based on computerized randomization. The first group receives HCG 10,000 units alone and the other group receives 10,000 units HGC plus 0.2 mg of Decapetyl subcutaneously. All of the oocytes are punctured under sonographic guidance 36 hours after the trigger. After 72 hours, 2 to 3 embryos will be transferred to the uterus and the rest will be frozen. After the puncture, progesterone will be prescribed for luteal phase support. On the third day after trigger and puncture, estradiol, LH, FSH and progesterone levels will be measured and so will the endometrial thickness. BHGC test will be performed and if the pregnancy test is positive, it would be considered a chemical pregnancy. Two weeks after a positive pregnancy test, transvaginal sonography will be performed to check the gestational sac. By detecting FHR in the sonogram clinical pregnancy is confirmed. Then the study will progress till 12th week and a sonography will be done to check the FHR and fetal health and to rule out abortion. These variables will be compared in both groups.

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2017091736235N1**

Registration date: **2017-11-05, 1396/08/14**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

**Registration date**

2017-11-05, 1396/08/14

**Registrant information**

**Name**

Niloofar Motaref

**Name of organization / entity**

Avicenna Infertility And Recurrent Abortion Institute

**Country**

Iran (Islamic Republic of)

**Phone**

+98 21 23519

**Email address**

n.motaref@avicenna.ac.ir

**Recruitment status**

**Recruitment complete**

**Funding source**

Avicenna Infertility and Abortion Research Institute

**Expected recruitment start date**

2017-10-23, 1396/08/01

**Expected recruitment end date**

2018-03-20, 1396/12/29

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparing the outcomes of dual trigger with GnRh agonist along with HCG versus HCG alone in normal responder patients in antagonist ART protocol

**Public title**
The effect of using HCG in combination with the GnRh agonist for improving IVF outcomes
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
Inclusion criteria: Infertility due to male factor, tubal factor or unexplained; IVF less than 2 times; age between 18 and 40; BMI between 18 and 30; normal PRL and TSH; FSH less than 10; The minimum sperm count, 10 million and the minimum 3% of the sperms should have normal morphology. Exclusion criteria: AFC more than 15; E2 more than 3000 at trigger day or AFC more than 20; sensitization to HCG or gonadotropins; FSH more than 10 at third day of cycles or AFC less than 5; AUB; documented uterine anomaly in hysterogram or HSG; endometriosis (grade 3 and 4); Diabetes or uncontrolled HTN, kidney or liver dysfunction; PCO; Cancer, tumor, or pituitary adenoma; Ovarian cysts; hydrosalpinx; intramural or submucosal myoma larger than 6cm
**Age**
From **18 years** old to **40 years** old
**Gender**
Female

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **164**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
**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**
Avicenna Research Institute Ethics Commitee
**Street address**
Avicenna Research Institute, Shahid Beheshti University, Velenjak Avenue, Chamran highway
**City**
Tehran
**Postal code**
1941913114
**Approval date**
2010-09-23, 1389/07/01
**Ethics committee reference number**
IR.ACECR.Avicenna.REC.1396.14

## Health conditions studied

### 1

**Description of health condition studied**
infertility
**ICD-10 code**
N97.9
**ICD-10 code description**
female infertility

## Primary outcomes

### 1

**Description**
Clinical pregnancy
**Timepoint**
28 days after transfer
**Method of measurement**
vaginal sonography

## Secondary outcomes

### 1

**Description**
Chemical pregnancy rate
**Timepoint**
14 days after transfer
**Method of measurement**
BHCG test

### 2

**Description**
Number of embryo formation
**Timepoint**
3 days after pancture
**Method of measurement**
Number

### 3

**Description**
OHSS
**Timepoint**
Till 2 weeks after ET
**Method of measurement**
sonography and symptoms

### 4

**Description**
Abortion
**Timepoint**
6th and 12th week of pregnancy
**Method of measurement**

sonography

**5**

**Description**
Number of oocyte (2PN)
**Timepoint**
Puncture day
**Method of measurement**
Number

## Intervention groups

**1**

**Description**
Control group will receive 10000 unit HCG for triggering final oocyte maturation
**Category**
Treatment - Drugs

**2**

**Description**
Intervention group will receive 10000 unit HCG pluse 0.2 mg decapeptyle for final maturation of oocyte
**Category**
Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Avicenna Infertility And Recurrent Abortion Research Institute
**Full name of responsible person**
Dr.Sara Mokhtar
**Street address**
No. 97, Yakhchal Junction, Shariati St
**City**
Tehran

## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Avicenna Research Institute
**Full name of responsible person**
Dr Seyed Ali Azin
**Street address**
Avicenna Research Institute, Shahid Beheshti University; Velenjak, Tehran
**City**
Tehran
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Avicenna Research Institute
**Proportion provided by this source**
100
**Public or private sector**
*empty*
**Domestic or foreign origin**
*empty*
**Category of foreign source of funding**
*empty*
**Country of origin**
**Type of organization providing the funding**
*empty*

## Person responsible for general inquiries

**Contact**
**Name of organization / entity**
Avicenna Infertility And Recurrent Abortion Research Institute
**Full name of responsible person**
Dr Sara Mokhtar
**Position**
MD, OB&GYN, Infertility fellowship
**Other areas of specialty/work**
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## Person responsible for scientific inquiries

**Contact**
**Name of organization / entity**
Avicenna Infertility And Recurrent Aborton Research Institute
**Full name of responsible person**
Dr Zhaleh Zolghadri
**Position**
MD, OB&GYN, Infertility fellowship
**Other areas of specialty/work**
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## Person responsible for updating data

**Contact**

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Avicenna Infertility And Recurrent Abortion Research Institute

**Full name of responsible person**

Niloofar Motaref

**Position**

MD, OB&GYN, Assistant Infertility Fellowship

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*