

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 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 hystrogram 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 Committee

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 plus 0.2 mg decapeptide 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

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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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Full name of responsible person

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Institute

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Other areas of specialty/work

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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