Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Jun 2026

Comparative study of double recombinant HCG injection and HCG injection (alone and in combination with GNRH) on the pregnancy outcome of patients with poor response in the ovulation stimulation cycle (IVF / ICSI)

Protocol summary

Study aim

Comparative study of the outcome of assisted reproductive therapy using double recombinant HCG injection and HCG injection (alone and in combination with GNRH) in patients with poor response in the ovulation stimulation cycle (IVF / ICSI).

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 150 patients in three groups. Being the number of people in each group, we will use the Restricted randomization method of the block randomization method, so that from 15 blocks of 6, including 2 to A, 2 to B and 2 to C Will be formed.

Settings and conduct

People start gonadotropin on the third day after menstruation after ovulation. To perform oocyte triggering, patients are randomly divided into three groups. Isfahan Shahid Beheshti Hospital.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Bologna Criteria people Exclusion criteria: Patients who become infected with the coronavirus during the cycle, patients who have not responded appropriately to the ovulation stimulation cycle and do not actually have a follicle to empty, patients who have mistakenly taken drugs during the cycle.

Intervention groups

People receive gonadotropin from the third day of menstruation by stimulating ovulation after being in the IVF cycle.In the first group, HCG trigger with KARMA brand is given alone with a dose of 10,000 units. In the second group, HCG trigger with KARMA brand is mentioned in the amount of 5000 units with GNRHagonist with Decapeptyl 0.2 brand and in the third group, recombinant HCG with OVITREEL brand with a dose of 250 micrograms is given twice in 12 hours.

Main outcome variables

Comparison of the average number of oocytes obtained and the rate of chemical pregnancy, frequency of IMPLANTATION, frequency of CILINICAL PREGNANCY, frequency of ONGOING PREGNANCY is used in three study groups.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110908007513N16**
Registration date: **2022-04-16, 1401/01/27**
Registration timing: **prospective**

Last update: **2022-04-16, 1401/01/27**
Update count: **0**

Registration date

2022-04-16, 1401/01/27

Registrant information

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Hatav Ghasemi Tehrani
Name of organization / entity
Isfahan University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2022-05-05, 1401/02/15
Expected recruitment end date
2022-07-06, 1401/04/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparative study of double recombinant HCG injection and HCG injection (alone and in combination with GNRH) on the pregnancy outcome of patients with poor response in the ovulation stimulation cycle (IVF / ICSI)

Public title
comparative study of three ovulation trigger methods in IVF/ICSI in poor response
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
According to the Blogna (Bologna) criteria, people who meet the following two criteria are:1- Age over 40 years or risk factor to reduce ovarian reserve such as history of ovarian surgery, etc.2 - History of poor previous response to IVF (less than 3 oocytes in the previous cycle)Abnormal ovarian reserve test AFC (number of antral follicles) less than 5 to 7 or AMH (antimullerian hormone) less than 1/1
Exclusion criteria:
Patients who become infected with the coronavirus during the cycle, patients who do not respond well to the ovulation stimulation cycle and do not actually have a follicle to empty, patients who mistakenly take medication during the cycle.
Age
From **30 years** old to **43 years** old
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **150**
Randomization (investigator's opinion)
Randomized
Randomization description
To perform oocyte triggering, patients are randomly divided into three groups. Due to the small sample size and to ensure the balance of the number of people in each group, we will use the restricted randomization method of block randomization and thus 15 out of 15 blocks including 2 Up to A, 2 to B and 2 to C will be formed.
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients who are eligible to enter the study are placed in one of three drug classes without the patient knowing, the results of the study after IVF are confidentially provided to a statistician for analysis.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
دانشگاه علوم پزشکی اصفهان
Street address
Isfahan University of Medical Sciences- Hezar jarib Ave. - Isfahan
City
Isfahan
Province
Isfehan
Postal code
73461-81746
Approval date
2022-03-12, 1400/12/21
Ethics committee reference number
IR.ARI.MUI.REC.1400.123

Health conditions studied

1

Description of health condition studied
infertility
ICD-10 code
N97
ICD-10 code description
Female infertility

Primary outcomes

1

Description
Comparison of the mean number of oocytes obtained and the rate of positive pregnancy serum test, frequency of pregnancy sac viscosity on ultrasound, frequency of fetal heart rate on ultrasound, frequency of pregnancy continuity up to 12 weeks of pregnancy are used in the three study groups.
Timepoint
The time of oocyte count after ovuum pickup and the time of positive pregnancy test 2 weeks after embryo transfer and the time of pregnancy sac evaluation week after embryo transfer and the time of implantation test 5 weeks after embryo transfer and the time of pregnancy

test 12 weeks in 12 weeks of pregnancy

Method of measurement

Evaluation of oocyte count after ovum pickup under a microscope to evaluate pregnancy test with HCG beta titration blood test and examination of pregnancy and pregnancy bags at 12 weeks with ultrasound

Secondary outcomes

1

Description

nothing

Timepoint

nothing

Method of measurement

nothing

Intervention groups

1

Description

Intervention group: Intervention group: in the control group for triggering the traditional HCG method with KARMA brand alone is given at a dose of 10,000 units. In the first intervention group HCG with KARMA brand at a dose of 5000 units with GNRHagonist and in the second intervention group recombinant HCG with OVITREEL brand dose 250 micrograms are given twice in 12 hours.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

isfahan shahid beheshti hospital

Full name of responsible person

Hatav Ghasemi Tehrani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Hatav Ghasemi Tehrani

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data

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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