

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparision of corifollitropin alfa versus recombinant FSH in poor ovarian responders

Protocol summary

Study aim

Comparision of corifollitropin alfa versus recombinant FSH in poor ovarian responders

Design

Clinical trial with a control group, with parallel groups, randomized, phase 3 on 90 patients. The rand function of Excel software was used for randomization.

Settings and conduct

This study is conducted as an RCT in 1401-1403 in the IVF department of Taleghani Hospital, Infertility Department. Patients with previous poor response in ivf cycles are assigned to two groups receiving corifollitropin alfa and recombinant FSH, which are assigned to one of the two treatment methods based on the randomization method with permutation blocks. will be divided

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with poor ovarian response in at least one previous ivf cycle, less than 40 years old, who had at least two of the following criteria: AFCL<5, AMH<1.2ng/dl, less than 3 oocytes in the previous cycle
Study exclusion criteria: uterine anomalies, history of untreated endocrine problems, heart, lung and liver problems and severe and uncontrolled underlying disease, unilateral or bilateral hydrosalpinx, prohibition of gonadotropin use, egg donors, severe male infertility (azoospermia, oligoasthenoteratospermia), stage 4 endometriosis, BMI <18 or >30
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Intervention groups

patients with poor ovarian response in at least one previous ivf cycle, less than 40 years old, who had at least two of the following criteria: AFCL<5, AMH<1.2ng/dl, less than 3 oocytes in the previous cycle

Main outcome variables

the number of oocytes obtained, the number of embryoblasts and the number of blastocytes obtained, the fertilization rate, implantation rate, and pregnancy rate.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221016056198N1**

Registration date: **2022-11-22, 1401/09/01**

Registration timing: **registered_while_recruiting**

Last update: **2022-11-22, 1401/09/01**

Update count: **0**

Registration date

2022-11-22, 1401/09/01

Registrant information

Name

Nazanin Hajizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2243 2600

Email address

hajizadeh.nazanin94@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-19, 1401/07/27

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of corifollitropin alfa versus recombinant FSH in poor ovarian responders

Public title
evaluation the effect of Alnavar drug on patients with low ovarian reserve in ivf cycle

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with hystory of previous cycle ; that who fulfilled at least two of the following criteria were admitted:
Antral follicle count (AFC) < 5;Antimullerian hormone (AMH) < 1,1 ng/ml;Less than three oocytes obtained in the previous cycle;
Exclusion criteria:
uterine abnormalities, recent or current history of any current untreated endocrine abnormality, unilateral or bilateral hydrosalpinx contraindications for the use of gonadotropins

Age
From **18 years** old to **40 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients with previous poor response in ivf cycles will be divided into two groups receiving corifollitropin alpha and recombinant FSH, which will be assigned to one of the two treatment methods based on randomization with replacement blocks with random EXCEL software. All patients will be informed about the study method and cost before entering the study. The advantages and disadvantages of the performed treatment will be informed and an informed consent form will be obtained.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
In reproduction and infertility, poor response to ovarian stimulation is one of the important problems and challenges of Bronchis, which causes additional costs, multiple cycles, discouragement and hopelessness in patients, and despite the use of different treatment regimens to manage this special group of patients, there is no single protocol. Corivoltropin alfa (CFA) is a long-acting gonadotropin designed as a stable follicular stimulator with the ability to simplify ovarian stimulation, given that one subcutaneous injection can replace the first seven injections of each cycle. follicle stimulating hormone (FSH). This is especially important considering

the psychological discomfort and despair and the high rate of abandonment of continuing IVF treatment in these patients.

Secondary Ids
empty

Ethics committees

1
Ethics committee
Name of ethics committee
Ethic committe of Shahid Beheshti University of Medical Sciences
Street address
Velenjak.shahid arabi street
City
Tehran
Province
Tehran
Postal code
1985717413
Approval date
2022-11-13, 1401/08/22
Ethics committee reference number
IR.SBMU.RETECH.REC.1401.520

Health conditions studied

1
Description of health condition studied
diminished ovarian reserve in IVF cycle
ICD-10 code
N97.8
ICD-10 code description
Female infertility of other origin

Primary outcomes

1
Description
The rate of continuous pregnancy is defined despite the intrauterine gestational sac with a fetal pole that shows cardiac activity during the 9th to 10th week of pregnancy.
Timepoint
9-10week after embryo transfer
Method of measurement
trans vaginal sonography

2
Description
Clinical pregnancy rate, which is defined as the presence of an intrauterine gestational sac in the 7th week of pregnancy
Timepoint
7week after embryo transfer

Method of measurement

trans vaginal sonography

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

Implantation rate per number of transferred embryos

Timepoint

3-5 weeks after embryo transfer

Method of measurement

trans vaginal sonography

Intervention groups**1****Description**

Intervention group that recieved corifolitropin alfa(Elonva),100 microgeram,start at 2th day of mense,Behestan daroo factory

Category

Treatment - Drugs

2**Description**

Control group that recieved recombinant FSH,follitropin alfa,cinnal f,150 mg,cinnagen drug factory

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Taleghani Infertility Clinic

Full name of responsible person

Nazanin Hajizadeh

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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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

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

10

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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Nazanin Hajizadeh

Position

Assistant fellowship

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

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Position

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Latest degree

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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

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Nazanin Hajizadeh

Position

Assistant Fellowship

Latest degree

Specialist