Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 May 2026

Comparison of efficacy Cinnal-F and Gonal-F on infertility treatment(ICSI)

Protocol summary

Summary

To consider of internal production of follitropin alfa or Cinnal-F drug which is similar to Gonal-F drug (which is produced by Ares Serono, Geneva, Switzerland) in treatment of infertility patients, it is supposed that to evaluate this comparison make be helpful especially in the setting of expenditures. Main objectives: Determination of implantation success rate in both group of Cinnal-F and Gonal-F subjects (ICSI/ET) Avicenna Infertility Clinic. Determination of success pregnancy rate in both group of Cinnal-F and Gonal-F subjects (ICSI/ET) Avicenna Infertility Clinic. Secondary objectives: Comparison of implantation success rate between both group of Cinnal-F and Gonal-F subjects (ICSI/ET) Avicenna Infertility Clinic. Comparison of pregnancy rate between both group of Cinnal-F and Gonal-F subjects (ICSI/ET) Avicenna Infertility Clinic. Success rate determination in both group (Cinnal-F and Gonal-F subjects (ICSI/ET) Avicenna Infertility Clinic) with differentiation of age, BMI, duration of drug stimulation, estradiol level on HCG prescription day, MII oocyte number, embryo number,... This prospective randomized clinical trial were conducted in infertility subjects of Avicenna Infertility Clinic with main reason of male factor. They were divided randomly in two group included 42 subjects in every group. All participants gave written consent prior to enrollment in the program project, according to the principles of the ethics committee of Avicenna Research Institute. Inclusion criteria include: FSH(Follicular Stimulating Hormon)≤ 10, normal blood prolactin, no pathology in uterus and adnexa, regular menses (25-35 days), with no history of more than three times ICSI cycles, with various types of infertility causes includes: PCOD, tubal factor, male factor, unexplained infertility, PGD, mild and moderate endometriosis. Exclusion criteria were: systemic diseases, BMI (Body Mass Index) ˃30, history of severe OHSS (Ovarian Hyper Stimulation Syndrome), history of poor respond in previous cycles, history of any pathology in uterus and adnexa. All patients underwent the protocol of long ICSI cycles treatment. After suppression of ovaries,patients received 150IU/d SC Cinnal-F or Gonal-F randomly for 5days from third day of menses after confirming of effective pituitary down regulation; it had been accomplished by no follicles 10 mm in diameter by vaginal sonography.Human chorionic gonadotropin(hCG) 5000-1000IU IM (IBSA)was administered 34-36 hours before oocyte retrieval to stimulate the final stages of follicular development by assistance of vaginal ultra-sonography when we inspected at least two follicles measure 17-18 mm in mean diameter and others routinly14-16 mm. After oocyte retrieval, we determined the number and maturity of oocytes (MII, MI, G.V.) and furthermore, specified the fertilization rate, the number and quality of the embryos on the following days. Clinical pregnancy and fetal sac at 6 weeks of pregnancy was validated by measurement of β-hCG and repeat after 48 hours and vaginal ultra-sonography respectively.

General information

Acronym

Cinnal-F

IRCT registration information

IRCT registration number: **IRCT2015110313907N2**
Registration date: **2016-05-15, 1395/02/26**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-05-15, 1395/02/26

Registrant information

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Name of organization / entity

Avicena Research Institute

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Recruitment status
Recruitment complete
Funding source
Avicenna Infertility Clinic (AIC); Cinnagen pharmaceutical Co.

Expected recruitment start date
2014-04-21, 1393/02/01
Expected recruitment end date
2015-03-19, 1393/12/28
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of efficacy Cinnal-F and Gonal-F on infertility treatment(ICSI)

Public title
Comparison of efficacy Cinnal-F and Gonal-F on infertility treatment(ICSI)
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: FSH <10; normal prolactinemia; no pathology in uterus and adenexae; regular menses between 25-35 days; not more than three times ICSI in history; variable factors of infertility. Exclusion criteria: systemic diseases; BMI>30; histort of severe OHSS; Hx. of poor response in previous cycles; any pathology in uterus and anenexae.
Age
From **18 years** old to **38 years** old
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **142**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Double 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 (ARI)
Street address
No.97 Yachtchal street , Shariati street
City
Tehran
Postal code
1941913114
Approval date
2015-11-17, 1394/08/26
Ethics committee reference number
IR.ACECR.Avicenna.REC.1394.16

Health conditions studied

1

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

Primary outcomes

1

Description
Number of MII oocytes
Timepoint
During ovum pick up
Method of measurement
By observing under electron microscopy by embryologist

Secondary outcomes

1

Description
Number of grade A embryos
Timepoint
after 3 days of development at laboratory
Method of measurement
Observing by embryologist under electron microscopy

Intervention groups

1

Description
In this study,the patients were prescribed OCP in previous mense and according to the kind of stimulation protocol (long ,short, antagonist) in further menstrual cycle the physicians were prescribed follitropin alfa known as Gonal-F as control group and the other group(

as case group) follitropin alfa made by Iranian pharmaceutical Co.to the patients.If the patients has needed HMG drugs, they will be added to treatment.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Avicenna Infertility Clinic

Full name of responsible person

Fatemeh Arjmand Teymouri

Street address

No.97 Yachtchal street , Shariati street

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Avicenna Infertility Clinic Co.

Full name of responsible person

Professor Mohammad Mehdi Akhondi

Street address

No.97 Yachtchal street , Shariati street

City

Tehran

Grant name

113641

Grant code / Reference number

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

Yes

Title of funding source

Avicenna Infertility Clinic Co.

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Cinnagen Pharmaceutical Co.

Full name of responsible person

Azhdarzadeh Morteza

Street address

No.56, Azimi street, Phase 1, Ekbatan, Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Cinnagen Pharmaceutical Co.

Proportion provided by this source

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 Clinic

Full name of responsible person

Fatemeh Arjmand Teymouri

Position

Fellowship in inferitlity(AIC)

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

AIC(Avicenna Infertility Clinic)

Full name of responsible person

Fatemeh Arjmand Teymouri

Position

Clinician/fellowship in infertility

Other areas of specialty/work

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Person responsible for updating data

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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