Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of using of recombinant Fsh long acting with or without hMG in IVf/ICSI cycles

Protocol summary

Summary

This study aimed ist comparing two long-acting antagonist regimen (Alvnva) with or without HMG In this study. 200 infertile patients based on 2011 ESHRE Criteria Characteristics of patients with poor ovarian response and without any disease were randomly divided into two groups according to a random numbers table. Antagonists are prescribed in both groups for ovarian stimulation.In group 1 (intervention group) a dose of 150 mg corrifollitropin alfa on the third day of the menstrual cycle are prescribed then on the seventh day after cycles , antagonist drug, Orgalutran, .5 mg daily wii be administerated. Control group in the third day of the menstrual cycle. ,Corrifolitropin alfa 150 mcg dose group received and the only recombinant FSH during the first seven days of daily monitoring cycle will receive. In both groups IN Day 7 of ovarian stimulation will be underwent transvaginal ultrasound by a physician who specializes in obstetrics and gynecology that do not have any knowledge about groups A and B., Then in both groups number of oocytes, number of embryos, and stimulated during pregnancy and abortion rates will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201404065181N13**
Registration date: **2014-06-02, 1393/03/12**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2014-06-02, 1393/03/12

Registrant information

Name

Batool Rashidi

Name of organization / entity

Vali E Asr Reproductive Health Research Center

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical sciences ,Vice Chancellor for research

Expected recruitment start date

2014-12-20, 1393/09/29

Expected recruitment end date

2016-05-30, 1395/03/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of using of recombinant Fsh long acting with or without hMG in IVf/ICSI cycles

Public title

Comparison of using of recombinant Fsh long time with or without hMG in IVf/ICSI cycles

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria:All patients agreed upon ESHRE Criteria 2011 ,advanced maternal age(>40 years)؛ previous poor ovarian respond (POR)؛ abnormal ovarian reserve Test (AFC=5-7, AMH=0.5-1.1)are enrolled. Exclusion Criteria:Cigaret user; history of ovarian cyst or surjeri in

ovary;primary sensitivity to Cinal Or Gonal-F ; Tumors depended to Sex in reproductive systhem ;Adrenal failure or oncontrlod Thyroid;andometriosis;couple chromosomal difficulties;ovulatory dysfunction (hypogonadic or hypergonadic infertility , hyperprolactinemia,thyroid disease, neoplastic ovary and adrenal,Kushing syndrome).

Age
From **20 years** old to **35 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **200**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tehran University of Medical sciences ,Vice Chancellor for research

Street address
Tehran University Building,Ghods Street,Keshavarz Blvd

City
Tehran

Postal code

Approval date
2014-04-30, 1393/02/10

Ethics committee reference number
93-01-39-25430

Health conditions studied

1

Description of health condition studied
Female infertility associated with anovulation

ICD-10 code
N97.0

ICD-10 code description
Female infertility associated with anovulation

Primary outcomes

1

Description
Mature oocyte

Timepoint
time of getting oocyte

Method of measurement
microscopic assay

2

Description
number of fetus

Timepoint
two days after getting of oocytes

Method of measurement
microscopic assay by embryologists

Secondary outcomes

1

Description
days of ovulation induction

Timepoint
Medication at the time of ovulation induction

Method of measurement
Patient records

2

Description
abortion

Timepoint
two weeks after embryo transfer

Method of measurement
transvaginal sonography and blood test

3

Description
pregnancy

Timepoint
two weeks after embryo transfer

Method of measurement
transvaginal sonography and blood test

Intervention groups

1

Description
Control group: A dose of 150 mcg corrifolitropin alfa received on the third day of the menstrual cycle , Antagonist drug Orgalutran, 5 mg is given on the seventh day. Then, during the monitoring cycle of seven days, if needed, will receive only the daily recombinant FSH. Ovarian response is followed by vaginal ultrasound,

when at least one follicle greater than 18 mm and there were at least three follicles larger than 14-15 mm, HCG Pregnyl) will be injected with a dose of 10,000 units.

Category

Treatment - Drugs

2

Description

Intervention group: A dose of 150 mcg corrifolitropin alfa is administrated on the third day of the menstrual cycle. Antagonist drug Orgalutran, 5 mg is given on the seventh day. Then on the seventh day after the cycle if needed, hMG will administrated. Ovarian response is followed by vaginal ultrasound, when at least one follicle greater than 18 mm and there were at least three follicles larger than 14-15 mm, HCG Pregnyl) will be injected with a dose of 10,000 units.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Valie Asr infertility Clinic

Full name of responsible person

Dr,Batool Rashidi

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

vhice chancellor of

Full name of responsible person

DR,KARBAKHSH

Street address

Tehran University Building,Ghods Street,Keshavarz Blvd.

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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

vhice chancellor of

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

Vali-e-Asr reproductive HealthnResearch center

Full name of responsible person

Dr,Batoolashidi

Position

Professor

Other areas of specialty/work

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Person responsible for scientific inquiries

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Vali-asr Reoroductive Health Research Center

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Dr,Batool Rashidi

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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