

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Comparison of the clinical outcome of ovarian stimulation with hMG + rFSH versus rFSH + rLH in infertile patients undergoing IVF / ICSI .

Protocol summary

Summary

Clinical pregnancy outcomes of controlled ovarian stimulation with recombinant-FSH plus recombinant-LH versus human Menopausal Gonadotropin plus recombinant-FSH has become the object of interest. This is a randomized clinical trial study held among 140 patients referring to infertility clinic in Valiasr hospital between 2014 -2016. Patients enrolled in this study according to a set of inclusion criteria (aged 20-35 years, Tubal or unexplained infertility , The absence of systemic disease, ovarian and no history of failed IVF) and randomly were divided into two groups. The first group (n=70) received oral contraceptive, GnRH, rFSH and hMG. The second group (n=70) , received oral contraceptive, GnRH, rFSH and rLH. Follicular growth was assessed by ultrasonography in every other day. Ovum Pick-Up (OPU) and then about two to three days after oocyte retrieval, embryo transfer (ET) were performed. Fecundity, and the embryos were assessed by embryologists. We assessed the outcomes such as chemical and clinical pregnancy, live birth rate and abortion rate in this study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016092720351N3**

Registration date: **2016-10-31, 1395/08/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-10-31, 1395/08/10

Registrant information

Name

Ensieh Shahrogh Tehraninejad

Name of organization / entity

Tehran University Of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Vice President of Research , Tehran Medical University.

Expected recruitment start date

2014-10-22, 1393/07/30

Expected recruitment end date

2016-06-20, 1395/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the clinical outcome of ovarian stimulation with hMG + rFSH versus rFSH + rLH in infertile patients undergoing IVF / ICSI .

Public title

Comparison of the Clinical pregnancy outcomes of ovarian stimulation with hMG + rFSH or rFSH + rLH methods in infertile patients.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: aged 20-35 years;Tubal or unexplained infertility, regular menstruation cycle between 21 and 35 days; Normal function of uterus according to hysterosalpingography; hysteroscopy or transvaginal

ultrasonography; Normal ovaries according to transvaginal ultrasonography during past 6 months prior to study and compatible with normal adnexa and normal ovarian anatomy; Serum FSH level less than 8 IU/l. Exclusion Criteria: Patients with other ovulation disorders such as hypo and hyper-gonadotropic; hypo gonadism; hyper-prolactinemia; thyroid disorders; ovarian or adrenal neoplasms; Cushing syndrome; previous history of systemic diseases such as endocrine and metabolic disorders and a previous history of inappropriate ovarian response to stimulation with gonadotropins (poor responders), prior history of more than 3 unsuccessful IVF; any malformation of sexual organs were excluded

Age

From **20 years** old to **38 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **140**

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**

Ethics Committee of Tehran University of Medical Sciences

Street address

Medical School, Ghods Street.

City

Tehran

Postal code

14194

Approval date

2014-03-05, 1392/12/14

Ethics committee reference number

911290028

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, unspecified

Primary outcomes**1****Description**

Chemical pregnancy

Timepoint

two weeks after embryo transfers

Method of measurement

Blood test

2**Description**

Clinical Pregnancy

Timepoint

three weeks after seeing sac fetus

Method of measurement

transvaginal sonography

3**Description**

Live birth

Timepoint

after delivery

Method of measurement

Live birth

4**Description**

Abortion

Timepoint

two weeks after embryo transfers

Method of measurement

transvaginal sonography

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

Number of oocyte

Timepoint

six day after treatment

Method of measurement

Transvaginal sonography

2**Description**

Number of embryo

Timepoint

one day after oocyte pick up
Method of measurement
See under a microscope by a specialist in embryology

Intervention groups

1

Description

TheFirst Interven group (n=70) , received oral contraceptive, GnRH, rFSH and rLH ,150-300 unit subcutaneously.

Category

Treatment - Drugs

2

Description

The second Intervention group (n=70) received oral contraceptive, GnRH, rFSH 150-300 Unit subcutaneosly and 75 Unit of HMG

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Vali Asr Infertility Clinic

Full name of responsible person

Ensieh Shahrokh Tehraninejad

Street address

Valiasr Infertility Clinic , Imam Khomeini Hospital,Keshavarz Blvd.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor or Tehran University of Medical Sciences

Full name of responsible person

Dr.Masoud Younesian

Street address

Floor N.6, Central Bulding , Ghods Street.

City

Tehran

Grant name

پایان نامه دوره رزیدنتی

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor or Tehran University of Medical Sciences

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

School of Medicine, Tehran University of Medical Sciences.

Full name of responsible person

Mina Farshbaf Taghinejad

Position

Residency in Gynecology

Other areas of specialty/work

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Full name of responsible person

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Position

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Other areas of specialty/work**Street address**

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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