

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Administration of bolus follicle stimulating hormone (FSH) with trigger dose human chorionic gonadotropin (hCG) in prevention of ovarian hyperstimulation syndrom (OHSS)

Protocol summary

Summary

this study is designed for evaluate the efficacy of FSH in preventing OHSS, 70 women recruite for this study are : 25 to 40 years old,under a long agonist GnRH suppression IVF protocol at infertility department of Shariati hospital,with >20 follicles in ART cycles ultrasonography, They prospectively randomize to two strategy groups (gp1&2) for the prevention of OHSS. In gp1 (35 patient) cases give 450 IU of FSH at the time of the hCG trigger. For gp2 (35 patients) only hCG trigger administer. Patients will follow at days 3, 10 post oocyte retrieval. Symptoms of OHSS (lower abdominal discomfort, abdominal distension, nausea and/or vomiting, rapid weight gain, dyspnea,and progressive oliguria), volumes of ovaries and ascites will observe. Patients will divide to 3 groups, mild/moderate/severe OHSS. Number of metaphase II oocytes, fertilization rate and clinical pregnancy will check.

General information

Acronym

FSH,hCG,OHSS

IRCT registration information

IRCT registration number: **IRCT201407206063N3**

Registration date: **2014-08-11, 1393/05/20**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-08-11, 1393/05/20

Registrant information

Name

Fateme Sarvi

Name of organization / entity

Shariati Hospital, Fertility center

Country

Iran (Islamic Republic of)

Phone

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fsarvi@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University Of Medical Science

Expected recruitment start date

2014-07-30, 1393/05/08

Expected recruitment end date

2014-08-21, 1393/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Administration of bolus follicle stimulating hormone (FSH) with trigger dose human chorionic gonadotropin (hCG) in prevention of ovarian hyperstimulation syndrom (OHSS)

Public title

FSH effect in OHSS prevention

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:25 to 40 years old woman;under a long agonist suppression IVF protocol at infertility department of Shariati hospital; with >20 follicles in ART cycles ultrasonography, exclusion criteria:no trend to contribution.

Age

From **25 years** old to **40 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **70**

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 Science and Health Services

Street address

Ghods St, Keshavarz Blvd

City

Tehran

Postal code

1417614411

Approval date

2014-07-06, 1393/04/15

Ethics committee reference number

93/854/130/

Health conditions studied**1****Description of health condition studied**

OHSS

ICD-10 code

N98.1

ICD-10 code description

Hyperstimulation of ovaries

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

OHSS severity

Timepoint

days 3,10 after ovarian puncture

Method of measurement

sign,symptom and vaginal sonography

2**Description**

clinical pregnancy rate

Timepoint

2 weeks after transfer

Method of measurement

vaginal sonography

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

number of oocyte collected

Timepoint

day of puncture

Method of measurement

counting

2**Description**

number of M2 oocyte

Timepoint

day of puncture

Method of measurement

counting

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

cases give one dose of 450 IU of FSH sub cutaneous at the time of the hCG trigger. Patients will followed at days 3, 10 post oocyte retrieval. Symptoms of OHSS (lower abdominal discomfort, abdominal distension, nausea and/or vomiting, rapid weight gain, dyspnea, and progressive oliguria), volumes of ovaries and ascites will observe .

Category

Treatment - Drugs

2**Description**

For control group hCG trigger administer as usual method , then they will followe at days 3, 10 post oocyte retrieval. Symptoms of OHSS (lower abdominal discomfort, abdominal distension, nausea and/or vomiting, rapid weight gain, dyspnea, and progressive oliguria), volumes of ovaries and ascites will observe .

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Hospital, Infertility Centre

Full name of responsible person

Leila Arshadi

Street address

Amirabad Ave, Gisha Brd

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Science and Health Service

Full name of responsible person

Leila Arshadi

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Amirabad Ave, Gisha Brd

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Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Science and Health Service

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

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Full name of responsible person

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Position

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Web page address

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