

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jul 2026

The effect of low dose hCG with GnRH agonist in decreasing rate of ovarian hyper stimulation syndrome in IVF cycles in Omid clinic and Shariati hospital in Teharn in 1394 and 1395.

Protocol summary

Summary

The purpose of study is evaluation of the effect of low dose hCG with GnRH agonist in decreasing rate of ovarian hyper stimulation syndrome (OHSS) in IVF cycles. This study is a single blind randomized clinical trial which is done on infertile women who are referred for IVF in Omid clinic and Shariati hospital in 1394 and 1395. Eighty infertile women are enrolled in two groups, 40 women in interventional group and 40 women in control group. Inclusion criteria are infertile women with following conditions: 18-39 year old; Normal FSH level; AMH>3.5 ng/ml; Poly cystic ovary (AFC>24); Previous ovarian hyper stimulation syndrome; In the day of oocyte retrieval the number of follicles bigger than 18mm>16 or Estradiol>4000 pg/ml. Maternal age greater than 40 year or hypothalamic dysfunction is excluded from the study. Interventional group receives GnRH agonist and after 36 hours low dose hCG is injected. Control group receives GnRH agonist and low dose hCG at the same time. After 36 hours, in both groups oocyte retrieval is performed guided by transvaginal sonography. Symptoms and signs of OHSS are evaluated during 2 weeks after oocyte retrieval. Pregnancy test is checked 2 weeks after embryonal transfer. Main outcome of this study is symptoms and signs of OHSS (Abdominal pain, Oliguria, Weight gaining, Nausea and Vomiting) which are evaluated during 2 weeks after oocyte retrieval.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016031427045N1**
Registration date: **2016-05-09, 1395/02/20**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-05-09, 1395/02/20

Registrant information

Name

Venus Chegini

Name of organization / entity

Tehran University of Medical Sciences, Shariati Hospital

Country

Iran (Islamic Republic of)

Phone

+98 21 8800 8810

Email address

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Tehran University of Medical Sciences

Expected recruitment start date

2015-12-28, 1394/10/07

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

The effect of low dose hCG with GnRH agonist in decreasing rate of ovarian hyper stimulation syndrome in IVF cycles in Omid clinic and Shariati hospital in Teharn in 1394 and 1395.

Public title

The effect of low dose hCG with GnRH agonist in decreasing rate of ovarian hyper stimulation syndrome in IVF cycles.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Infertile women with following conditions: 18-39 year old; Normal FSH level; AMH>3.5 ng/ml; Poly cystic ovary (AFC>24); Previous ovarian hyper stimulation syndrome; in the day of oocyte retrieval the number of follicles bigger than 18mm>16 or Estradiol>4000 pg/ml Exclusion criteria: Maternal age>40 year; Hypothalamic dysfunction.

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: **80**

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

Ethic Committee of Tehran University of Medical Sciences

Street address

Ethic Committee, Tehran University of Medical Sciences, Poorsina Street, Tehran

City

Tehran

Postal code

1417653761

Approval date

2015-12-28, 1394/10/07

Ethics committee reference number

IR.TUMS.REC.1394.1508

Health conditions studied

1

Description of health condition studied

Female infertility

ICD-10 code

N98.1

ICD-10 code description

Complications associated with artificial fertilization, Hyperstimulation of ovaries

Primary outcomes

1

Description

ovarian hyper stimulation syndrome

Timepoint

2 weeks after embryonal transfer

Method of measurement

Transvaginal ultrasonography and examination

Secondary outcomes

1

Description

Chemical Pregnancy

Timepoint

14 days after embryonal transfer

Method of measurement

βhCG titration

2

Description

Implantation rate

Timepoint

4 weeks after embryonal transfer

Method of measurement

Observationl of gestational sac in transvaginal sonography

3

Description

Clinical pregnancy rate

Timepoint

2 weeks after positive pregnancy test

Method of measurement

Observation of gestational sac in transvaginal sonography

Intervention groups

1

Description

Interventional group receives 150 IU FSH daily from the second day of menses. When the 14 mm follicles is observed in transvaginal ultrasound GnRH antagonist

(Cetrorelix) 0.25mg subcutaneously daily is added. After the observation of at least two 18mm follicles, GnRH agonist (Bucerellin 0.5 mg) is injected. After 36 hours, low dose hCG is injected and oocyte retrieve is performed under general anesthesia. Three days after fertilization, transcervical embryo transfer will be carried out. Symptoms and signs of OHSS (Abdominal pain, Oliguria, Weight gaining, Nausea and Vomiting) are evaluated during 2 weeks after oocyte retrieval. Pregnancy test is checked 14 days after embryonal transfer. 2 weeks after positive test, by the aid of transvaginal ultrasound the pregnancy sac and fetal heart are detected.

Category

Prevention

2

Description

Control group, receives 150 IU FSH daily from the second day of menses. When the 14 mm follicles is observed in transvaginal ultrasound GnRH antagonist (Cetrorelix) 0.25mg subcutaneously daily is added. After the observation of at least two 18mm follicles, GnRH agonist (Bucerellin 0.5 mg) and low dose hCG are injected. After 36 hours oocyte retrieve is performed under general anesthesia. Three days after fertilization, transcervical embryo transfer will be carried out. Symptoms and signs of OHSS (Abdominal pain, Oliguria, Weight gaining, Nausea and Vomiting) are evaluated during 2 weeks after oocyte retrieval. Pregnancy test is checked 14 days after embryonal transfer. 2 weeks after positive test, by the aid of transvaginal ultrasound the pregnancy sac and fetal heart are detected.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Omid clinic and Shariati Hospital

Full name of responsible person

Dr. Venus Chegini

Street address

Shariati Hospital, North Karegar Street, Tehran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Tehran University of Medical Sciences

Full name of responsible person

Dr Masood Younesian

Street address

Vice Chancellor for Research, Tehran University of Medical Sciences, Keshavarz Boulevard, Tehran

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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

Vice Chancellor for Research, 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

Tehran University of Medical Sciences, Shariati Hospital

Full name of responsible person

Dr Venus Chegini

Position

Obstetric and Gynecologic Resident

Other areas of specialty/work

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Person responsible for scientific inquiries

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Other areas of specialty/work
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City

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