Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

City

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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Full name of responsible person

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Person responsible for updating data

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Tehran University of Medical Sciences, Shariati Hospital
Full name of responsible person
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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