

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

Investigation of outcome of assessment reproduction treatment and prevention of ovarian hyper stimulation syndrome in GnRH agonist protocol compared to GnRH antagonist protocol

Protocol summary

Summary

Objective: to compare GnRH antagonist and agonist protocols regarding the outcome and rate of OHSS. Subjects: women who were referred to the infertility center of Beheshti hospital, Isfahan, Iran, for ART . 136 patients were randomly allocated to 2 groups: 67 patients were treated with GnRH agonist, 69 patients were treated with GnRH antagonist. Inclusion criteria: age ≤ 35 , FSH level ≤ 10 IU/liter. Exclusion criteria: hyperprolactinemia, thyroid dysfunction, uterine abnormality, severe endometriosis. Group A, a daily dose of Buserelin 500 μ g given SC and commenced 21st day of cycle, and vaginal ultrasonography continued onward until estradiol on the 2st day of cycle. Group B, GnRH antagonist was administered. Ovarian stimulation was started on the 2nd day of the cycle by SC injection of 75 IU of FSH daily. On the 6th day of stimulation, 0.25 mg Cetorelix was initiated. Based on the ovarian response detected by ultrasonography, gonadotropin dose was adjusted in both groups. Administration of Buserelin and Cetorelix was continued until the time of HCG injection. When at least 3 follicles with a mean diameter of 18 mm were developed, HCG 10,000 IU was injected IM. At this stage, endometrial thickness was studied Trans vaginal ultrasonographically, and after 36 hours, oocyte retrieval was performed. After IVF or ICSI, Cyclogest 800 mg was prescribed daily to provide luteal phase support and continued till the activity of FHR was confirmed TVS. Sixteen days after the oocyte retrieval, serum HCG level was checked to determine chemical pregnancy. TVS was carried out for clinical determination of pregnancy.

General information

Acronym

GnRH

IRCT registration information

IRCT registration number: **IRCT201205309910N1**

Registration date: **2012-06-24, 1391/04/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-06-24, 1391/04/04

Registrant information

Name

Setare Nasiri Zeydi

Name of organization / entity

Isfahan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Private

Expected recruitment start date

2011-01-22, 1389/11/02

Expected recruitment end date

2012-02-12, 1390/11/23

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of outcome of assessment reproduction

treatment and prevention of ovarian hyper stimulation syndrome in GnRH agonist protocol compared to GnRH antagonist protocol

Public title

Comparing two different drug methods for infertility treatment by assisted reproduction techniques (ARTs)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: undergoing assisted reproduction techniques (ARTs) for the first time, age ≤ 35 years and serum FSH level ≤ 10 IU/liter. Exclusion criteria: women with the previous history of IVF or ICSI; patients who had hyperprolactinemia, thyroid dysfunction, uterine abnormality, severe endometriosis and secondary infertility.

Age

To **35 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **136**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Isfahan University of Medical Sciences

Street address

Hezar jerib street

City

Isfahan

Postal code**Approval date**

2011-11-09, 1390/08/18

Ethics committee reference number

390428

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

infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

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

Ovarian hyperstimulation syndrome

Timepoint

10 days after HCG injection and during primary Trimester

Method of measurement

as presence of enlarged ovarian cysts more than 12 by 12 cm, ascites, pleural and/or pericardial effusion, electrolyte imbalance, hypovolemia, and hypovolemic shock

2**Description**

Fertility

Timepoint

after primary Trimester

Method of measurement

ultrasonography

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

number of retrieved oocytes

Timepoint

2 weeks after intervention

Method of measurement

number of retrieved oocytes in retrieval day

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

Group A: a daily dose of Buserelin 500 μ g given SC and commenced 21th day of cycle, and vaginal ultrasonography continued onward until estradiol on the 2nd day of cycle.

Category

Treatment - Drugs

2**Description**

Group B: GnRH antagonist was administered. Ovarian stimulation was started on the 2nd day of the cycle by

SC injection of 75 IU of FSH daily. On the 6th day of stimulation, 0.25 mg Cetorelix was initiated. Based on the ovarian response detected by ultrasonography, gonadotropin dose was adjusted in both groups. Administration of Buserelin and Cetorelix was continued until the time of HCG injection. When at least 3 follicles with a mean diameter of 18 mm were developed, HCG 10,000 IU was injected IM. At this stage, endometrial thickness was studied Trans vaginal ultrasonographically, and after 36 hours, oocyte retrieval was performed. After IVF or ICSI, Cyclogest 800 mg was prescribed daily to provide luteal phase support and continued till the activity of FHR was confirmed TVS.16days after the oocyte retrieval, serum HCG level was checked to determine chemical pregnancy. TVS was carried out for clinical determination of pregnancy

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Infertility center of Beheshti hospital

Full name of responsible person**Street address**

Beheshti hospital, Isfahan

City

Isfahan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Isfahan University of Medical Sciences

Full name of responsible person

Dr.Taleb azarm

Street address

Isfahan University of Medical Sciences, Hezar jerib st.

City

Isfahan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Isfahan 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**

Isfahan University of Medical Sciences

Full name of responsible person

Setare Nasiri Zeydi

Position

Obstetric and gynecology resident

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Masoumeh Hashemi

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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