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 µg 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 Cetrorelix was initiated. Based on the ovarian response detected by ultrasonography, gonadotropin dose was adjusted in both groups. Administration of Buserelin and Cetrorelix 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

Country

Iran (Islamic Republic of)

Phone

+98 31 1651 2267

Email address

setare_n99@yahoo.com

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 ≤35years 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 µg 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 Cetrorelix was initiated. Based on the ovarian response detected by ultrasonography, gonadotropin dose was adjusted in both groups. Administration of Buserelin and Cetrorelix 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

Other areas of specialty/work

Street address

Isfahan University of Medical Sciences

City

Isfahan

Postal code

Phone

+98 911 255 6829

Fax

Email

setare_n99@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Isfahan University of Medical Sciences

Full name of responsible person

Setare Nasiri Zeydi

Position

obstetric and gynecology resident

Other areas of specialty/work

Street address

Isfahan University of Medical Sciences

City

Isfahan

Postal code

Phone

+98 911 255 6829

Fax

Email

setare_n99@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Full name of responsible person

Masoumeh Hashemi

Position

Phd student in Reproductive Health

Other areas of specialty/work

Street address

Isfahan University of Medical Sciences

City

Isfahan

Postal code

Phone

Fax

Email

mhashemi_ob@yahoo.com

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