Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of fixed versus flexible GnRH antagonist protocols outcomes in controlled ovarian stimulation for IVF/ICSI in polycystic ovary syndrome.

Protocol summary

Summary

The aim of this study is evaluation the ART outcome in women with PCOS. Whose are candidate for controlled ovarian stimulation for IVF with GnRH antagonist fixed or flexible protocols. In the fixed GnRH antagonist protocol, gonadotropin stimulation with 150 IU of gonadotropins rFSH is initiated on day 3 of menstruation after discontinuation of OCPs. Then Cetrotide 0.25 mg daily s.c is administrated on day 6 of gonadotropin stimulation. In the flexible GnRH antagonist protocol daily s.c administration of Cetrotide 0.25 mg is initiated when at least one follicle measuring 12 mm; is presented .The starting dose of rFSH was 150 IU/day for all patients in both groups. Ultrasound monitoring continued until hCG administration. When three follicles reach a mean diameter of _17 mm, hCG Is administered i.m.. 34–36 h after 10,000 IU hCG injection, transvaginal ultrasound-guided oocyte retrieval is performed

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201101135181N5**
Registration date: **2013-02-25, 1391/12/07**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-02-25, 1391/12/07

Registrant information

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences -Vice-chancellor for research -Tehran University of Medical Science r

Expected recruitment start date

2012-12-21, 1391/10/01

Expected recruitment end date

2013-07-21, 1392/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of fixed versus flexible GnRH antagonist protocols outcomes in controlled ovarian stimulation for IVF/ICSI in polycystic ovary syndrome.

Public title

Evaluation of fixed versus flexible GnRH antagonist protocols outcomes in controlled ovarian stimulation in polycystic ovary syndrome.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : infertile patients with poly cystic ovary syndrome;20-40 years old Body mass index BMI 20-30 kg/m2 Exclusion criteria: endometriosis;ovarian cysts; pelvic neoplasia of the uterine and ovarian ; endocrine

disorders (disorders of tyroid , prolactin); male factor infertility; blocked fallopian tubes in HSG, FSH levels on the 3th day of menestration >12miu/ml, previous OHSS; history of RIF (RECURRENT IMPLANTATION FAILURE)

Age
From **20 years** old to **40 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not 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 Sciences

Street address
5th floor-Ghods Ave-Keshavarz Blvd

City
tehran

Postal code

Approval date
2010-09-23, 1389/07/01

Ethics committee reference number
19567

Health conditions studied

1

Description of health condition studied
POLY CYSTIC OVARIAN SYNDROME

ICD-10 code
E28.2

ICD-10 code description
Sclerocystic ovary syndrome Stein-Leventhal syndrome

Primary outcomes

1

Description
clinical pregnancy rate

Timepoint
4-6weeks after emberyo transfer

Method of measurement
the presence of gestational sac with fetal heart beat detectionat 6–7 weeks of gestation

Secondary outcomes

1

Description
dose of cetrotide

Timepoint
at the end of controlled ovarian stimulation period

Method of measurement
dose of administration of Cetrotide

2

Description
duration of administration of Cetrotide

Timepoint
at the end of controlled ovarian stimulation period

Method of measurement
days of administration of Cetrotide

3

Description
Ongoing pregnancy

Timepoint
the presence of gestational sac with fetal heart beat detection at 12 w of gestation

Method of measurement
the presence of gestational sac with fetal heart beat detection at 12 w of gestation

4

Description
duration of administration of rFSH

Timepoint
at the end of controlled ovarian stimulation period

Method of measurement
days of administration of rFSH

5

Description
dose of rFSH

Timepoint
at the end of controlled ovarian stimulation period

Method of measurement
dose of administration of rFSH

6

Description
hospitalization rate due to OHSS

Timepoint
at the controlled ovarian stimulation period -UNTIL 4 weeks after pregnancy
Method of measurement
days of hospitalization due to OHSS

Intervention groups

1

Description
Intervention group 1 : In the fixed group , on day 3 of menstruation, gonadotropin stimulation with 150 IU subcutaneous of rFSH is initiated, Then Cetrotide 0.25 mg daily subcutaneous is administrated on day 6 of gonadotropin stimulation. When diameter of at least 3 follicles is more than 17 mm, HCG 1000IU intra muscular is administrated . Then 34-36 hours ovarian puncture under general anesthesia will done .
Category
Treatment - Drugs

2

Description
Group 2(flexible):Third day of menstrual bleeding, gonadotropin 150IU rFSH (Gonalf) is began daily subcutaneously. Then if there is a follicle ≥ 12 mm ,Cetrotide 0.25 mg is administered subcutaneously. HCG 1000IU intra muscular is administrated . Then 34-36 hours ovarian puncture under general anesthesia will done . In both groups ,rFSH gonadotropin is adjusted based on monitoring ultrasonographic and Cetroid injection until HCG injection will continue.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Vali-e-Asr reproductive health research center of Tehran -infertility clinic
Full name of responsible person
Street address
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical SciencesVice-chancellor of research,
Full name of responsible person
MIS Azvan
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Vice-chancellor of research of Tehran University of Medical Sciences-5th floor-Ghods Ave-Keshavarz Blvd.
City
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 SciencesVice-chancellor of research,
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
Vali-e-Asr reproductive HealthnResearch center
Full name of responsible person
Tahereh Behroozi lak
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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