

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 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

Name

Batool Rashidi

Name of organization / entity

Vali E Asr Reproductive Health Research Center

Country

Iran (Islamic Republic of)

Phone

+98 21 6693 9320

Email address

bhrashidi@tums.ac.ir

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 thyroid , prolactin); male factor infertility; blocked fallopian tubes in HSG, FSH levels on the 3th day of menstration >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 embryo transfer

Method of measurement

the presence of gestational sac with fetal heart beat detection at 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

Street address

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 Behrooziiak

Position

Associate professor

Other areas of specialty/work

Street address

,Imamkhomeini Hospital,Val-asr Hospital,Vali-e-Asr reproductive HealthnResearch center

City

Tehran

Postal code

Phone

+98 21 6693 9320

Fax

+98 21 6658 1658

Email

t.behrooz2@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Vali-e-Asr reproductive health research center

Full name of responsible person

DrBtool Hosein Rashidi

Position

Assistant professor

Other areas of specialty/work

Street address

-Keshavarz Blvd. Tehran Emam KHomeini complex hospitaVali-e-Asr reproductive health research centerl

City

Tehran
Postal code
Phone
+98 21 6119 2449
Fax
+98 21 6658 1658
Email
bhrashidi@tums.ac.ir t.behrooz2@yahoo.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Vali-e-Asr reproductive health research center
Full name of responsible person
Dr.Tahereh Behrooz Lak
Position
assistant
Other areas of specialty/work
Street address
Vali-e-Asr reproductive health research center-
Keshavarz Blvd. Tehran
City

Tehran
Postal code
Phone
+98 21 6119 2449
Fax
Email
t.behrooz2@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