

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Comparison of GnRH agonists and antagonists the outcome IVF/ICSI in women with polycystic ovary syndrome

Protocol summary

Summary

Ovarian hyper stimulation syndrome (OHSS) is one of the Major problems of ovarian stimulation during cycles of the patient's polycystic ovarian syndrome (PCOS) that treatment of IVF/ ICSI. In recent years, there have been reports that the incidence of OHSS is lower of the GnRH antagonists than of the GnRH agonists. GnRH antagonists may be useful for the PCOS patients. Yet, few studies have been published to compare the GnRH antagonists than of the GnRH agonists in PCOS patients. The purpose of this study was to compare GnRH antagonists and agonist in patients IVF/ICSI. 120 PCOS infertile women were enrolled in the study of Fatemeh Zahra Infertility Center. Inclusion criteria for this study included: (1) meeting of 2003 Rotterdam PCOS criteria ovulation...) and exclusion criteria (More than two abortions...). Patients are divided randomly into two groups. The women, who were in the group which received GnRH agonists, started one LD tablet daily from the second or third day of the cycle for a period of 14-21 days. In the day 21, they had injection cycle of 500mg GnRH agonists subcutaneously. Antagonist group, ovulation starts with Gonal F injection from day 2 - 3 periods. A drug starts in women less than 30 years with 150 units and in women more than 30 years with 225 units. β HCG was tested in volunteers following 14 days after embryo transfer to the uterus. Individuals with positive β HCG test underwent fetal ultrasound at sixth to seventh weeks of gestation. Preimery results are including a positive pregnancy test, and secondary outcomes included duration of ovarian stimulation, number of medications, and the cost done.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201402041760N30**

Registration date: **2014-03-03, 1392/12/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-03-03, 1392/12/12

Registrant information

Name

Nargess Gholizadeh Pasha

Name of organization / entity

Fatemehzahra Infertility Reproductive Health Research Center, Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

zahra@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research and Technology, Babol University of Medical Sciences

Expected recruitment start date

2013-05-15, 1392/02/25

Expected recruitment end date

2014-01-21, 1392/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of GnRH agonists and antagonists the outcome IVF/ICSI in women with polycystic ovary

syndrome

Public title
Comparison of GnRH agonists and antagonists the outcome IVF/ICSI in women with polycystic ovary syndrome

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: PCOs; having two of the three diagnostic criteria Rotterdam 2003(Irregular menstruation oligomenorrhea, amenorrhea and irregular bleeding); hyperandrogenism(Hirsutism, severe acne, hair loss); obesity; polycystic ovaries on ultrasound to rule out specific diseases such as disorders of the hypothalamus, pituitary or other causes hyperandrogenism ; age $\leq$ 35 years; FSH <12 mlu / ml on days 2-3 of the cycle Exclusion criteria: history of more than two abortions; in laparoscopic uterine anomaly, hysteroscopy & hysterosonography; ovarian cysts.

Age
From **18 years** old to **35 years** old

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The ethics committee of Babol University of Medical sciences

Street address

Ganjafoz Avenue, Babol University of Medical sciences

City

Babol

Postal code

Approval date

2013-05-14, 1392/02/24

Ethics committee reference number

2458/30/پ/ژ

Health conditions studied

1

Description of health condition studied

Polycystic ovarian syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

Primary outcomes

1

Description

Pregnancy

Timepoint

7-6 weeks to see the gestational sac

Method of measurement

Ultrasound

Secondary outcomes

1

Description

Duration of ovarian stimulation

Timepoint

Duration of drug use

Method of measurement

Clinical

2

Description

Number of drugs

Timepoint

Duration of treatment

Method of measurement

clinical

3

Description

The cost

Timepoint

Time to confirm pregnancy

Method of measurement

Amount spent

Intervention groups

1

Description

Intervention Groups: Agonist group GNRH, starting the

cycle period of 2-3 days, 14-21 days, take one tablet daily for 21 days and the LD cycle Busereline 500mg Super artifact construction company (Aventis) will subcutaneously. After down regulation, stimulation with HMG or Gonal F Manufacturing Co. (IBSA, MARCK) begin until at least two follicles with a diameter of 18 mm will continue.

Category

Treatment - Drugs

2

Description

Control Groups: Aldo Group ovulation period of 2-3 days with Gonal F starts in people younger than 30 years with 2 injections (150 units) and in women older than 30 years with 3 injections (225 units) starts. When the follicle diameter reached 10 mm, Serum E2 > 600pg/ml, the daily Cetorelix 0.25mg (manufactured by MERCK) started and will continue until the day of HCG injection subcutaneously.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemehzahra Fertility & reproductive Health
Research Center

Full name of responsible person

Dr. Naghmeh Noorani

Street address

Fatemehzahra Fertility & reproductive Health
Research Center, Noshirvani street

City

Babol

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology, Babol
University of Medical Sciences

Full name of responsible person

Dr. Ali Bijani

Street address

Ganjafroz Avenue, Babol University of Medical
Sciences, Vice Chancellor for Research and
Technology

City

Babol

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 and Technology, Babol
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

Fatemehzahra Fertility & reproductive Health
Research Center

Full name of responsible person

Marmar Firoozpour Bandepei

Position

Midwifery Expert

Other areas of specialty/work

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Fatemehzahra Infertility & reproductive Health
Research Center

Full name of responsible person

Dr. Mahtab Zeinalzadeh

Position

Gynecologist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Nargess Gholizadeh Pasha

Position

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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