Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

Effects of GnRH Antagonist versus GnRH Agonist Protocol on ART outcomes in Poor ovarian Responders

Protocol summary

Summary

GnRH agonist protocol prevents premature ovulation and early corpus luteum. The disadvantages are taking high doses and prolonged stimulation of the ovaries to respond better that the eggs are smaller and lower quality recycled. Recently, GnRH antagonists have been used in the middle of the cycle to prevent premature LH surge in the early follicular phase and decreased during ovarian stimulation. In this study, the effect of GnRH antagonists is compared with the long protocol GnRH agonists in patients with poor ovarian response. 100 infertile patients selected with inclusion criteria (number of oocytes recovered in less than 5 ...) and exclusion criteria (presence of chronic diseases ...), they were randomly divided into two groups: GnRH antagonists and GnRH agonists. GnRH agonist group, use of oral LD on cycle's days 2-3 for 14-21 days, as they will consume in Cycle days 21 Busereline 500 µg (Superfact) subcutaneously. After down regulation, stimulation with HMG is started and continued until at least two follicles with a diameter over mm 18. Busereline will continue daily until HCG (IU 1000) injections. Antagonist group GnRH, when the follicle diameter mm 10 Cetrorelix 0.25 mg subcutaneous injection start and continue would be to inject Day HCG. Fourteen days after oocyte retrival a quantitative serum value of BHCG was obtained, with a result of >10 UI/L being considered positive. Pregnancy is confirmed by the presence of gestational sac in ultrasound 7-6 weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201302271760N21**
Registration date: **2013-08-28, 1392/06/06**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2013-08-28, 1392/06/06

Registrant information

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Nargess Gholizadeh Pasha
Name of organization / entity
Fatemehzahra Infertility Reproductive Health Research Center, Babol University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

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

Expected recruitment start date

2013-03-20, 1391/12/30

Expected recruitment end date

2013-10-22, 1392/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of GnRH Antagonist versus GnRH Agonist Protocol on ART outcomes in Poor ovarian Responders

Public title

Effects of GnRH Antagonist versus GnRH Agonist Protocol

on ART outcomes in Poor ovarian Responders

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Infertile women who underwent IVF process and poor ovarian response; The number of oocytes recovered in less than 5; Serum estradiol levels on the day of HCG injection is less than pg / ml 600; Serum FSH levels in Male than 3 mIU / ml 12; Has over 37 years of age; Cessation of ovarian cycles due to poor response. Exclusion criteria: Chronic diseases; Diabetes; Any endocrine disease; Submucosal polyps; Leiomyoma and uterine septum.

Age

From **37 years** old to **45 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

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

The ethics committee of Babol University of Medical sciences

Street address

Ganjafroz Avenue, Babol University of Medical sciences

City

Babol

Postal code

Approval date

2013-02-05, 1391/11/17

Ethics committee reference number

200/30/پ-ژ

Health conditions studied

1

Description of health condition studied

Poor ovarian Responders

ICD-10 code

E28.8

ICD-10 code description

Other ovarian dysfunction

Primary outcomes

1

Description

Pregnancy

Timepoint

7-6 weeks to see the gestational sac

Method of measurement

Ultrasound

Secondary outcomes

1

Description

Endometrial thickness

Timepoint

Day of HCG injection

Method of measurement

Ultrasound

2

Description

Estradiol levels

Timepoint

Day of HCG injection

Method of measurement

Ultrasound

3

Description

The number of oocytes recovered

Timepoint

Day puncture

Method of measurement

Laboratory

4

Description

The duration of ovarian stimulation

Timepoint

Duration of drug use

Method of measurement

Clinical

5

Description

No. of fertilized oocytes

Timepoint

Day of embryo transfer

Method of measurement

Laboratory

6

Description

The amount of transferred embryos

Timepoint

Day of embryo transfer

Method of measurement

Laboratory

7

Description

The number of canceled cycles

Timepoint

Before embryo transfer

Method of measurement

Clinical

8

Description

Pregnancy than to transfer

Timepoint

16 days after embryo transfer

Method of measurement

Laboratory

9

Description

The incidence of ovarian hyperstimulation syndrome (OHSS)

Timepoint

After puncture

Method of measurement

Clinical & Laboratory

10

Description

The total amount of FSH

Timepoint

48 hours before puncture

Method of measurement

Laboratory

Intervention groups

1

Description

Intervention group: Agonist (3-2 days after onset of LD cycles lasting 21-14 days, take one tablet daily for 21 days and the cycle Busereline 500 µg (Super facts) will subcutaneously. Later down regulation, stimulation with HMG begin until at least follicle diameters exceeding 2 mm 18 will continue. supermodel facts will continue daily until IU 1000 HCG injection)

Category

Treatment - Drugs

2

Description

Control group: Antagonist (GnRH when the follicle diameter 10mm, reach to daily injections of HCG, Cetrorelix 0.25 mg subcutaneously daily will)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemehzahra Fertility & reproductive Health Reseach Center

Full name of responsible person

Samaneh Niksimaei

Street address

Fatemehzahra Fertility & reproductive Health Reseach Center, Noshirvani street

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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

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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 Reseach Center

Full name of responsible person
Nargess Gholizadeh Pasha

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M.A/Responsible for Public Affairs of Research Center

Other areas of specialty/work

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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