

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Gonadotropin-releasing hormone antagonist vs agonist in Iranian normo-responders undergoing in vitro fertilisation: A Randomized Clinical Trial

Protocol summary

Summary

In this Randomized clinical trial, 300 normo-responders undergoing IVF were randomly divided to GnRh agonist (n=150) and GnRh antagonist (n=150) groups. In the agonist group on cycle day 21, Busereline acetate was started as 0.5 mg daily (S.C.) injection until menstruation had begun. At day 3 of next menstrual cycle, the dose of Busereline was diminished to 0.2 mg and rFSH was started and the dose was adjusted on the basis of follicle graph using Gonal-F and HMG. In the antagonist group rFSH treatment was begun on day 3 of menstrual cycle and the dose was adjusted on the basis of follicle graph using Gonal-F and HMG. When there was one follicle 14mm in diameter antagonist (Cetrotide), 0.25 mg S.C. daily dose was administrated until the day of HCG administration. In both groups when at least 2 follicles 18-20 mm in diameter were seen, rFSH and HCG (10000 IU, IM) was injected. The main outcome measurements were chemical, clinical and ongoing pregnancy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138902283950N1**

Registration date: **2011-06-19, 1390/03/29**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-06-19, 1390/03/29

Registrant information

Name

Mina Jafarabadei

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2008-01-01, 1386/10/11

Expected recruitment end date

2010-01-01, 1388/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Gonadotropin-releasing hormone antagonist vs agonist in Iranian normo-responders undergoing in vitro fertilisation: A Randomized Clinical Trial

Public title

Gonadotropin-releasing hormone antagonist vs agonist in Iranian normo-responders undergoing in vitro fertilisation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age <38 years; normal basal serum FSH; $20 \leq \text{BMI} < 30 \text{ kg/m}^2$; regular menstrual cycle.

Exclusion criteria: Polycystic ovary syndrome; severe endometriosis; history of poor response in previous treatment cycles; history of repeated IVF failure more than 3 cycles failed.

Age

From **18 years** old to **38 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **300**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Vali- e-Asr Reproductive Health Research Center

Street address

Reproductive Health Research center, Emam Hospital, Keshavarz Blvd.

City

Tehran

Postal code**Approval date**

2007-12-09, 1386/09/18

Ethics committee reference number

0071/I/ρ

Health conditions studied**1****Description of health condition studied**

response to controlled ovarian stimulation

ICD-10 code

Z31.2

ICD-10 code description

In vitro fertilization

Primary outcomes**1****Description**

pregnancy

Timepoint

after one cycle of controlled ovarian stimulation

Method of measurement

chemical, clinical and ongoing pregnancy

Secondary outcomes**1****Description**

number of retrieved oocytes

Timepoint

after one cycle of controlled ovarian stimulation

Method of measurement

counting by light microscope

Intervention groups**1****Description**

In the agonist group on cycle day 21, Busereline acetate was started as 0.5 mg daily (S.C.) injection until menstruation had begun. At day 3 of next menstrual cycle, the dose of Busereline was diminished to 0.2 mg and rFSH was started and the dose was adjusted on the basis of follicle graph using Gonal-F and HMG. When at least 2 follicles 18-20 mm in diameter were seen, rFSH and HCG (10000 IU, IM) was injected.

Category

Treatment - Drugs

2**Description**

In the antagonist group rFSH treatment was begun on day 3 of menstrual cycle and the dose was adjusted on the basis of follicle graph using Gonal-F and HMG When there was one follicle 14mm in diameter antagonist (Cetrotide), 0.25 mg S.C. daily dose was administrated until the day of HCG administration. When at least 2 follicles 18-20 mm in diameter were seen, HCG (10000 IU, IM) was injected.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Reproductive Health Research Center, Tehran University of Medical Sciences

Full name of responsible person**Street address****City**

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Ashraf Moini

Street address

Reproductive Health Research Center, Emam Hospital, Keshavarz Blvd.

City

Tehran

Grant name

طرح های تحقیقاتی

Grant code / Reference number

007

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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**

Reproductive Health Research Center, Tehran University of Medical Sciences

Full name of responsible person

Dr Mina Jafarabadi

Position

Assistant professor

Other areas of specialty/work**Street address**

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Person responsible for scientific inquiries

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Full name of responsible person

Dr Mina Jafarabadi

Position

Assistant professor

Other areas of specialty/work**Street address**

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Web page address

Person responsible for updating data

Contact

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