

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison between ultrashort gonadotropin-releasing hormone agonist and flare microdose protocol in ART poor responders

Protocol summary

Summary

Background: Management of poor responders to ovarian stimulation who encompass about 9-18% of the patients undergoing IVF, is the most difficulties in assisted reproductive techniques (ART). Objective: The present study focused on the use of ultrashort GnRH agonist in antagonist protocol and microdose GnRH agonist flare-up in poor responders to ovarian induction. Materials and Methods: One hundred and twenty candidates of ART that referred to Yazd Research and Clinical Center for Infertility (From June 2007 to July 2009) who had a history of one or more failed IVF cycles with three or fewer retrieved oocytes, were prospectively randomized in two groups. In group I (60 patients), the microdose flare-up regimen and in group II (60 patients), the ultrashort GnRH agonist combined with fixed GnRH antagonist were used. Main outcomes measures included: the number of follicles and oocytes, endometrial thickness, clinical and chemical pregnancy and implantation rates.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201105096420N1**

Registration date: **2011-06-06, 1390/03/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-06-06, 1390/03/16

Registrant information

Name

Maryam Eftekhar

Name of organization / entity

Yazd Research and Clinical Center for Infertility

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Yazd Research and Clinical Center for Infertility, Shahid Sadoughi University of Medical Sciences

Expected recruitment start date

2007-06-21, 1386/03/31

Expected recruitment end date

2009-06-21, 1388/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between ultrashort gonadotropin-releasing hormone agonist and flare microdose protocol in ART poor responders

Public title

Comparison of two treatment protocol in assisted reproductive techniques (ART) poor responders

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: A history of one or more failed in IVF cycles which three or fewer oocytes were been retrieved or their serum steradiol's level in day of HCG injection was <500 pg/ml or FSH in day 3 of cycle was >10 or age>40 years. Exclusion criteria: Body mass index higher than 30 and endocrine or metabolic disorder,

endometriosis and severe male factor (azospermia).

Age

From **18 years** old to **45 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

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Yazd Research and Clinical Center for Infertility

Street address

Bouali Avenue, Safayeh

City

Yazd

Postal code

8916877391

Approval date

2009-01-05, 1387/10/16

Ethics committee reference number

2421

Health conditions studied

1

Description of health condition studied

Infertility

ICD-10 code

N97

ICD-10 code description

Female infertility

Primary outcomes

1

Description

Pregnancy

Timepoint

2 weeks

Method of measurement

BhcG Test

Secondary outcomes

1

Description

number of follicles

Timepoint

15 days

Method of measurement

Numbering

2

Description

quality of oocytes

Timepoint

15 days

Method of measurement

Observation by microscope according to Good
-postmature-degenerated

3

Description

the number of used gonadotropin ampoules

Timepoint

15 days

Method of measurement

Numbering

4

Description

Quality of embryo

Timepoint

15 days

Method of measurement

According to the symmetrics and exact of Blastomer
pieces

5

Description

Number of oocytes

Timepoint

15 days

Method of measurement

Numbering

6

Description

Chemical pregnancy

Timepoint

after 14 days of embryo transfer

Method of measurement

Measurement of serum B-hCG

7

Description

Clinical pregnancy

Timepoint

2-3 weeks after positive B-hCG

Method of measurement

observation of the fetal heart activity using a transvaginal ultrasonography

Intervention groups

1

Description

In group I, 0.05mg subcutaneous Buserelin (suprefact, serono) was injected two times per day from the day 1 of cycle and HMG (Menogon, Ferring) 300 IU per day intramuscular from day 3 of cycle. Follicular monitoring was started from day 9 of cycle by serial vaginal ultrasonography and then gonadotropin doses adjustment was done as required. hCG (pregnyl; NV organon, oss, Netherlands) 10000 IU was injected Intramuscular when at least 2 follicles \geq 18mm were noted on ultrasonography. Oocyte retrieval was scheduled 36 hours after hCG injection and conventional IVF or intracytoplasmic sperm injection (ICSI) was performed. Embryo transfer was done 48-72 hours after oocyte retrieval. The luteal phase support was initiated from the day of oocyte retrieval with 100 mg Progesterone in oil (Progesterone, Abureihan co., Tehran, Iran) per day.

Category

Treatment - Drugs

2

Description

In group II, ovulation induction was performed with Buserelin (suprefact, serono) 0.5mg SC per day started on day 1 of cycle and continued for 3 consecutive days . HMG (menogon, ferring) 300 IU per day was started on day 3 of cycle. GnRH antagonist (cetorelix, serono laboratories, Aubonne, Switzerland) 0.25mg sc per day was started when the follicle's size reach to 14mm. Follicular monitoring started from day 9 of cycle and hCG (pregnyl, NV organon, oss, Nether lands) 10000 IU was injected if at least 2 follicles \geq 17-18mm were noted on ultrasonography and Oocyte retrieval was scheduled 36 hours after hCG injection. Other steps was done like group I. In both groups, Serum B-hCG was measured after 14 days of embryo transfer. If B-hCG was Positive, the clinical pregnancy was confirmed by observation of the fetal heart activity using a transvaginal ultrasonography 4-5 weeks after oocyte retrieval. And then, the two groups were compared in number of follicles, serum estradiol levels, endometrial thickness, Number and quality of oocytes, number and quality embryo, implantation rate and clinical and chemistry pregnancy rate.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd Research and Clinical Center for Infertility

Full name of responsible person

Dr. Maryam Eftekhari

Street address

Boali Ave., Safayeh

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd Research and Clinical Center for Infertility

Full name of responsible person

Dr. Abbas Aflatoonain

Street address

Bouali Ave, Safayeh

City

Yazd

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yazd Research and Clinical Center for Infertility

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

Research and Clinical Center for Infertility

Full name of responsible person

Dr. Maryam Eftekhari

Position

Assisted professor of Obstetrics and Gynecology

Other areas of specialty/work

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Person responsible for updating data

Contact

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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