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

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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 emberyo

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 injectod Intramuscular when at least 2 follicles ≥ 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 (cetrorelix, 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 (pregnyle, NV orgaron, oss, Nether lands) 10000 IU was injected if at least 2 follicles ≥ 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 Possitive, 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 Eftekhar
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
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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
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
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Dr. Maryam Eftekhar
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Assisted professor of Obstetrics and Gynecology
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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