Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 2026

Comparison of Long protocol And Agonist-Antagonist protocol in the infertile normal responder patients undergoing ICSI cycles

Protocol summary

Summary

Comparison of Long and Agonist-Antagonist protocols for ovarian stimulation in normal responder patients undergoing Intra Cytoplasmic Sperm Injection . Randomized clinical trial. Under study population: Infertile normal responder patients referred to infertility clinic for ovarian stimulation under treatment of ICSI. Inclusion criteria: normal responder; BMI less than 30 . Exclusion criteria: low responder; high responder patients. In this study patients divided into two groups: In one group patients treating with Long protocol and other group treating with Agonist-Antagonist protocol. Sixty patients are in each group. After IVF, the results checked in short time and long time and effectiveness of these two protocol checked in clinical and chemical pregnancy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016022326711N1**
Registration date: **2016-04-11, 1395/01/23**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-04-11, 1395/01/23

Registrant information

Name

fateme fakhar moghadam

Name of organization / entity

tehran university

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2016-01-14, 1394/10/24

Expected recruitment end date

2016-05-13, 1395/02/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Long protocol And Agonist-Antagonist protocol in the infertile normal responder patients undergoing ICSI cycles

Public title

Comparison of Long protocol And Agonist-Antagonist protocol in the infertile normal responder patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: normal responder infertile patients included (It means age less than 40 and normal ovarian reserve(6<AFC<12) accompanying with 3.5>AMH>1); also patients had good response to previous ovarian stimulation: BMI more than 30 . Exclusion criteria: low responder patients; high responder patients; using donated oocyte and donated egg; single ovary; endometriosis; if patient's husband need to use TESE and PESA.

Age

No age limit

Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **120**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Tehran University of Medical Sciences
Street address
Tehran University of Medical Sciences, Keshavarz BLVD, Tehran
City
Tehran
Postal code
Approval date
2016-01-13, 1394/10/23
Ethics committee reference number
IR.TUMS.REC.1394.1647

Health conditions studied

1

Description of health condition studied
Infertility
ICD-10 code
N97
ICD-10 code description
Female infertility

Primary outcomes

1

Description
Number of oocyte metaphase 2
Timepoint
After ovarian puncture
Method of measurement
Microscope- by counting oocyte

Secondary outcomes

1

Description
Age
Timepoint
Chronological age
Method of measurement
Birth Certificate - year

2

Description
time of infertility
Timepoint
At first
Method of measurement
Interviews with patient - year

3

Description
Type of infertility
Timepoint
At first
Method of measurement
Interviews with patient - Infertility divided in two groups: primary (no pregnancy history) and secondary

4

Description
Chemical pregnancy
Timepoint
Two weeks after transfer
Method of measurement
Blood test - bhcg titration

5

Description
Clinical pregnancy
Timepoint
Four weeks after transfer
Method of measurement
Vaginal sonography - View gestational sac and fetal heart rate

6

Description
The number of matured follicle
Timepoint
Before puncture
Method of measurement
Vaginal sonography - The number of matured oocyte with size of18mm or more

7

Description
The number of antral follicle
Timepoint
At first
Method of measurement
Vaginal sonography - The number of antral follicle with size of 2-9 mm in follicular phase.

8

Description
The number of punctured oocyte
Timepoint
After puncture
Method of measurement
Microscope - The number of punctured oocyte.

9

Description
The number of fetus
Timepoint
After puncture
Method of measurement
Microscope-The number of fetuses after injection.

10

Description
The number of transferred fetus
Timepoint
In the time of transfer
Method of measurement
Microscope - The number of fetuses transfer in uterine.

11

Description
The days stimulation
Timepoint
At first of cycle
Method of measurement
Documents - The number of days that using gonadotropin

12

Description
Endometrial thickness
Timepoint
Before transfer
Method of measurement
Vaginal sonography - mm

13

Description
BMI
Timepoint
At first
Method of measurement
Examination of patient - Dividing weight in kg by the square of one's height in cm

14

Description
The number of drug used
Timepoint
In the end of treatment
Method of measurement
Documents - The number of drugs using for ovarian stimulation.

Intervention groups

1

Description
In Agonist -Antagonist protocol in second day of cycle agonist GNRH (DECAPEPTYL0.1MG)used SC for 3 days and then gonadotropin (Gonal-f) administered. After 6 days vaginal sonography done frequently and when one 14 mm follicle appears in sonography , antagonist GNRH (cerotide) used SC until two 18mm follicles appeared .Then HCG in 5000 unit injected IM and after36 hours oocytes punctured.
Category
Treatment - Drugs

2

Description
In Long protocol in second or third day of cycle OCP started for 21 days. In Mid-luteal phase agonist GNRH (SUPERFACT) administered for 7 days and menstruation started and In second or third day of next cycle the dose of agonist decrease to half of previous dose. Then gonadotropin (Gonal-f) administered. After 6 days vaginal sonography done frequently until two 18mm follicles appeared .Then HCG in 5000 unit injected IM and after36 hours oocytes punctured.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shariati Hospital
Full name of responsible person
Dr Fateme Fakhar Moghadam
Street address
Shariati Hospital, Jalal-Al-Ahmad BLV intersection Northern Kargar, Tehran
City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Dr Fateme Fakhar Moghadam

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Shariati Hospital, Jalal Al Ahmad Intersection, Northern Kargar Street, Tehran

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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
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
Shariati Hospital, Tehran University of Medical Sciences

Full name of responsible person
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General Medicine and Resident of Obstetrics and Gynecology

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Person responsible for scientific inquiries

Contact

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00

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Web page address

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