Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of double stimulation protocol to the approach using antagonist with high dose of gonadotropin in patients with poor ovarian response in avicenna infertility center

Protocol summary

Study aim

Investigation and comparison of the results of microinjection using the Double Stimulation protocol with high dose gonadotropin-antagonist protocol in patients with POR.

Design

Study type: Randomized clinical trial . Study group: Sixty patients with POR who nominated for microinjection and divided randomly into two groups of 30.

Settings and conduct

Firstly, the probable side effects of drugs competently were explained to the patients and written consents were obtained. In Double Stimulation group letrozol and clomifin pills were administrated since day 2, and gonadotropin since day 4 . In another group is started from 2 days after period and 450-600 units gonadotropin were used. Depending on ovules response the doses are adjusted. Both groups are investigated in terms of number and quality of ovules and embryos, pregnancy condition, and serum levels of progesterone, FSH, LH, and Estradiol. The study will be carried out in Tehran Avicenna infertility center.

Participants/Inclusion and exclusion criteria

Inclusion criteria : Aged over 40; history of less than 4 oocyte; abnormal ovarian reserve tests; previous ovary surgery; risk factors in weak ovary response. Exclusion criteria BMI value: 35 and higher; FSH more than 25; grade 3 endometriosis and higher; any contraindication for ovarian stimulation like uncontroled systemic dieases; intense male infertility according to WHO indexes

Intervention groups

Aim: improving ovarian response in POR patients. The effectiveness of two antagonist protocols with high doses of Gonadotropin and twice stimulation in follicular and luteal phases in terms of the number and quality of ovules and embryo will be carried out and finally the fertility rates will be compared.

Main outcome variables

Successful fertility rate, improved number and quality of embryos and ovules, high And qualitative , improved rate of chemical and clinical pregnancy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180219038792N1**
Registration date: **2019-01-02, 1397/10/12**
Registration timing: **retrospective**

Last update: **2019-01-02, 1397/10/12**
Update count: **0**

Registration date

2019-01-02, 1397/10/12

Registrant information

Name

Farnaz Montazeri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 23519

Email address

f.montazeri@ari.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-04, 1397/01/15

Expected recruitment end date

2018-11-06, 1397/08/15

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of double stimulation protocol to the approach using antagonist with high dose of gonadotropin in patients with poor ovarian response in avicenna infertility center

Public title
Comparison of double stimulation protocol with high dose of gonadotropin protocol in patients with poor ovarian response
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age over 40. History of getting less than four oocyte retival in previous cycle Abnormal ovarian reserve tests. History of previous ovarian surgery or history of chemotherapy Different risk factors involved in ovarian response weakness
Exclusion criteria:
BMI value is equal to 35 and higher FSH more than 25 Grade 3 endometriosis and higher Any contraindication for ovarian stimulation such as uncontrolled systemic diseases Sever male infertility based on WHO indexes
Age
From **40 years** old to **45 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
A random specific code was allocated for each of 500 poor responders. A sample size of 60 was calculated based on the relating formula. 60 patients with poor response were randomly selected and divided into two groups of 30. Group A was selected for intervention and group B was considered as control.
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
Ethics committee of avesina research institue
Street address
No. 97, Yakhchal Junction, Shariati St., Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1941913114
Approval date
2017-05-02, 1396/02/12
Ethics committee reference number
IR.ACECR.Avicenna.REC.1396.17

Health conditions studied

1

Description of health condition studied
Poor ovarian responds patients
ICD-10 code
E28
ICD-10 code description
Ovarian dysfunction

Primary outcomes

1

Description
1-The number of retrieved oocytes
Timepoint
Measuring the number of follicles in the first menstrual cycle and after taking ovulation-inducing drugs
Method of measurement
Ultrasouand system

2

Description
The number and quality of the obtained embryos
Timepoint
In follicular and luteal phase
Method of measurement
Ultrasouand system

3

Description
Measurement of serum Progesterone
Timepoint
On the day the gonadotropins started, and on the day of the trigger with Deca in the follicular and luteal phase
Method of measurement
ELISA

4

Description
Measurement of serum E2,
Timepoint
On the day the gonadotropins started, and on the day of the trigger with Deca in the follicular and luteal phase
Method of measurement
ELISA

5

Description
Measurement of serum LH
Timepoint
On the day the gonadotropins started, and on the day of the trigger with Deca in the follicular and luteal phase
Method of measurement
ELISA

6

Description
Measurement of serum FSH
Timepoint
On the day the gonadotropins started, and on the day of the trigger with Deca in the follicular and luteal phase
Method of measurement
ELISA

7

Description
The quantity of retrieved oocytes
Timepoint
Measuring in the first menstrual cycle and after taking ovulation-inducing drugs
Method of measurement
Ultrasouand system

Secondary outcomes

1

Description
The amount of pregnancy and successful birth
Timepoint
After 9 months
Method of measurement
Number of successful pregnancies and live births

Intervention groups

1

Description
This study is a prospective randomized clinical trial. Patients who are nominated for ICSI because of POR are divided into two groups of 30 individuals randomly. After completing the consent, they will be placed in Double Stimulation group or a high dose antagonist gonadotrophin. First group, the starting day of the menstrual period begins with letrozole and clomiphene, and from the fourth day starts 150 units of gonadotrophin.
Category
Treatment - Drugs

2

Description
Control group: second group from the second day of the menstrual cycle, gonadotrophin starts at a dose of 450-400 units, and the dose is adjusted depending on the response of the ovaries. Both groups were evaluated for the number and quality of oocytes and embryos obtained, pregnancy status and serum levels of FSH, LH, Estradiol, Progesterone.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
No. 97, Yakhchal Junction, Shariati St., Tehran, Iran
Phone: 23519-021
Full name of responsible person
Farnaz Montazeri
Street address
No. 97, Yakhchal Junction, Shariati St., Tehran, Iran
Phone: 23519-021
City
Tehran
Province
Tehran
Postal code
1941913114
Phone
+98 21 23519
Fax
+98 21 2264 4754
Email
f.montazeri@ari.ir
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iranian academic center for education culture and research
Full name of responsible person
Mohammad Reza Sadeghi
Street address
No. 97, Yakhchal Junction, Shariati St., Tehran, Iran
Phone: 23519-021
City
Tehran
Province
Tehran

Postal code
1941913114
Phone
+98 21 23519
Email
f.montazeri@ari.ir

Grant name

Grant code / Reference number

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

Title of funding source
Iranian academic center for education culture and research

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Iranian academic center for education culture and research

Full name of responsible person
Farnaz Montazeri

Position
Non-faculty specialist

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

Street address
No. 97, Yakhchal Junction, Shariati St., Tehran, Iran
Phone: 23519-021

City
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Province
Tehran

Postal code
19419113114

Phone
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Email
f.montazeri@ari.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iranian academic center for education culture and research

Full name of responsible person
Farnaz Montazeri

Position
Non-faculty specialist

Latest degree
Specialist

Other areas of specialty/work
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Phone
+98 21 23519

Email
f.montazeri@ari.ir

Person responsible for updating data

Contact

Name of organization / entity
Iranian academic center for education culture and research

Full name of responsible person
Farnaz Montazeri

Position
Non-faculty specialist

Latest degree
Specialist

Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form
Undecided - It is not yet known if there will be a plan to

make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available