Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

Comparison of luteal phase stimulation with follicular phase stimulation in poor ovarian response

Protocol summary

Study aim
Comparison of luteal phase stimulation with follicular phase stimulation in poor ovarian response

Design
Clinical trial with control group, with parallel groups, single-blind, randomized, phase 3 on 78 patients. Randomization will be done using 4 blocks designed with sealedenvelop.com software.

Settings and conduct
This study will be performed at Avicenna Infertility Center. Women are randomly divided into two groups.In the intervention group ovarian stimulation begins in the luteal phase and in the control group ovarian stimulation begins in the follicular phase. In both groups, GnRH antagonist is administered when the largest follicle is> 12 mm. Stimulation of ovulation using a GnRH agonist with 2 HCGs when at least one follicle> 18 mm is seen will be prescribed. Oocyte collection will be done by transvaginal ultrasound 36 hours later. Fertilization will take place after oocyte retrieval. The embryos are then frozen on the third or fifth day, and in another cycle, the uterus is prepared for embryo transfer and the embryos are transferred.Pregnancy test is done14 days after embryo transfer. Chemical and clinical pregnancy rates will be assessed.

Participants/Inclusion and exclusion criteria
- History of an ovulation stimulation cycle with less than 4 oocytes - AMH<1.1 ng/ml or AFC<5 - Total number of motile sperm at least 15 million - Normal uterus in ultrasound hysterosalpingography - Regular periods of 21-35 days - Indication for IVF - Compliance to participate and collaborate with study protocol - Signing informed consent

Intervention groups
Intervention group: ovarian stimulation in the luteal phase will be started on days 15-16 of the cycle. Stimulation will be performed using HCG. Control group: ovarian stimulation in the follicular phase is initiated at the beginning of the cycle. Stimulation will be performed using HCG.

Main outcome variables
Number of metaphase II oocytes

General information

Reason for update
The update is to change the sample size.

Acronym

IRCT registration information
IRCT registration number: **IRCT20210405050852N1**
Registration date: **2021-06-10, 1400/03/20**
Registration timing: **prospective**

Last update: **2023-03-01, 1401/12/10**
Update count: **1**

Registration date
2021-06-10, 1400/03/20

Registrant information

Name
Mozhgan Vahabi Dastjerdi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 2264 4701

Email address
vahabi.mozhgan@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-07-01, 1400/04/10

Expected recruitment end date
2021-12-31, 1400/10/10

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of luteal phase stimulation with follicular phase stimulation in poor ovarian response

Public title
Effect of luteal phase stimulation with follicular phase stimulation in poor ovarian response
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
History of an ovulation stimulation cycle with less than 4 oocytes AMH<1.1 ng/ml or AFC<5 The total number of motile sperm is at least 15 million Normal uterus in ultrasound and hysterosalpingography Regular periods of 21-35 days Indication for IVF Ability to participate and collaborate with study protocol Signature informed consent Under 40 years
Exclusion criteria:
History of ovarian surgery History of pelvic cytotoxic radiation exposure due to malignancy History of recurrent miscarriage Grade III or IV endometriosis Concomitant uterine pathology (adenomyosis, submucosal myoma, Asherman syndrome) Autoimmune disease
Age
From **18 years** old to **39 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **78**
Randomization (investigator's opinion)
Randomized
Randomization description
The Block randomization method was designed by an epidemiologist using STATA software version 13 and the number of blocks considered is 4. The random allocation list for patients was solely available to the epidemiologist. In order to hide the random allocation process, a total of 78 envelopes were prepared, and only the methodologist has been aware of the table of random numbers. When the doctor declared the patient's eligibility, the methodologist provided the doctor with the envelope. The group was selected based on the type of group mentioned in the envelope.
Blinding (investigator's opinion)
Single blinded
Blinding description
This is a single-blind study. The participants don't aware about grouping name and type of treatment in each group. In order to blind the patients participating in this study, all conditions will be the same between the two groups, so patients in the intervention and control groups will refer to the center on ovulation stimulation days in both groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Avicenna Research Institute (ARI)
Street address
No. 97, at the corner of the Yakhchal st, Shariati st, Avicenna Infertility Clinic
City
Tehran
Province
Tehran
Postal code
1941913114
Approval date
2021-03-09, 1399/12/19
Ethics committee reference number
IR.ACECR.AVICENNA.REC.1400.002

Health conditions studied

1

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

Primary outcomes

1

Description
Number of metaphase II oocyte
Timepoint
End of ovarian stimulation
Method of measurement
Observation of metaphase 2 oocytes extracted by the embryologist

Secondary outcomes

1

Description
Chemical pregnancy rate
Timepoint
14 days after transfer
Method of measurement
Beta-Human Chorionic Gonadotropin

2

Description
Clinical pregnancy
Timepoint
Pregnancy 7th weeks
Method of measurement
Detect of fetal heart beat on ultrasound

3

Description
Total number of embryos
Timepoint
After in vitro fertilization
Method of measurement
18-20 hours after in vitro fertilization

Intervention groups

1

Description
In this study, to compare the effect of luteal phase stimulation with follicular phase stimulation in patients with poor ovarian response, in the luteal phase group on days 15 to 16 of the menstrual cycle and when spontaneous ovulation is confirmed by transvaginal ultrasound and patients have one follicle at least 8 mm, start with 300 units of FSH plus 150 to 225 units of HMG plus 10 mg of medroxyprogesterone daily. Medroxyprogesterone is used to delay mensturation and stop the release of oocytes during mensturation. GnRH antagonist is given when the largest follicle is> 12 mm. Sono examination will be performed every 24 to 72 hours. Blood hormones will also be tested by checking estradiol and progesterone levels on the day of ovulation stimulation. Ovulation stimulation will be administered using a GnRH agonist with 2 Human chorionic gonadotropins when at least one follicle <18 mm is seen. Oocyte collection will be done by transvaginal ultrasound 36 hours later. Fertilization will take place after oocyte retrieval. Successful fertilization is diagnosed when two pronuclei are seen about 18-20 hours after insemination. The embryos are then frozen on the third or fifth day, and in another cycle, the uterus is prepared for embryo transfer and the embryos are transferred. 14 days after the transfer of the fetus, the pregnancy test will be requested and the rate of chemical and clinical pregnancy will be evaluated.
Category
Treatment - Drugs

2

Description
Control group: In patients in the control group (follicular phase stimulation group), ovarian stimulation begins on the second or third day of the cycle with 300 units of FSH plus 150 to 225 units of HMG. GnRH antagonist is given when the largest follicle is> 12 mm. Ultrasound examination will be performed every 24 to 72 hours. Blood hormone analysis will also be done by checking estradiol and progesterone levels on the day of ovulation stimulation, and ovulation stimulation by GnRH agonist along with 2 Human chorionic gonadotropins will be administered when at least one follicle <18 mm is seen. Fertilization will take place after oocyte harvest. Successful fertilization is diagnosed when two pronuclei are seen about 18-20 hours after inoculation. The embryos are then frozen on the third or fifth day, and in another cycle, the uterus is prepared for embryo transfer and the embryos are transferred. 14 days after the transfer of the fetus, the pregnancy test will be requested and the rate of chemical and clinical pregnancy will be evaluated.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Avicenna infertility clinic
Full name of responsible person
Simin Zafardoost
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No. 97, at the corner of the Yakhchal st, Shariati st, Tehran, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Avicenna University Jihad Infertility Center Avicenna
Full name of responsible person
Ramin Ghahremanzadeh
Street address
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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
Avicenna University Jihad Infertility Center Avicenna

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
Avicenna infertility clinic

Full name of responsible person
Mozhgan Vahabi Dastjerdi

Position
Infertility Fellowship

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Avicenna infertility center

Full name of responsible person
Mozhgan Vahabi Dastjerdi

Position
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Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Full name of responsible person
Mozhgan Vahabi Datjerdi

Position
Infertility Fellowship

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

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

Title and more details about the data/document

Comparison of luteal phase stimulation with follicular phase stimulation in poor ovarian response

When the data will become available and for how long

Up to one year after the publication of the article

To whom data/document is available

Other researchers and physicians

Under which criteria data/document could be used

Use in meta-analysis studies

From where data/document is obtainable

Avicenna infertility clinic, Dr. Mozhgan Vahabi datjerdi, 00982122644706

What processes are involved for a request to access data/document

Email to the responsible author, Dr. Mozhgan vahabi Dastjerdi

Comments