Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jul 2026

Comparison of ovarian stimulation in proliferative and luteal phases in an ovarian cycle (DuoStim method) in patients with poor ovarian response

Protocol summary

Study aim

General aim: to investigate the results of ovarian stimulation with the DuoStim protocol on patients with poor ovarian response and compare the results in the luteal and proliferative phase.

Design

In this study, there is only one intervention group and there is no control group. Each patient is subjected to gonadotropin stimulation in both ovarian phases (proliferative and luteal) and the results of both phases are compared. Clinical trial without control group, without randomization on 26 patients

Settings and conduct

26 infertile poor ovarian response patients referred to the infertility center of Shahid Beheshti Hospital in Isfahan The patients are subjected to ovarian induction in two proliferative and luteal phases with the DuoStim protocol. Blinding was not done in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women who are known as patients with poor response to ovulation stimulation according to diagnostic criteria. Exclusion criteria: Azoospermia / history of uterine surgery / severe endometriosis/ hydrosalpinx/ endocrine disorders / history of repeated abortions/repeated failure of implantation more than or equal to 3 times

Intervention groups

In the DuoStim method, ovarian stimulation is performed in both ovarian phases in all patients with poor ovarian response. In this study, there is only one intervention group and no control group.

Main outcome variables

Overall fertility percentage, the average number of oocytes and the average number of metaphase 2 oocytes after ovulation, the average number of embryos obtained after in vitro fertilization and the average quality of embryos obtained in the proliferative phase and luteal phase.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221001056068N1**
Registration date: **2022-11-22, 1401/09/01**
Registration timing: **registered_while_recruiting**

Last update: **2022-11-22, 1401/09/01**
Update count: **0**

Registration date

2022-11-22, 1401/09/01

Registrant information

Name

Safa Salehi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-10-02, 1401/07/10

Expected recruitment end date

2022-12-31, 1401/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of ovarian stimulation in proliferative and luteal phases in an ovarian cycle (DuoStim method) in patients with poor ovarian response

Public title
Comparing the effects of ovarian stimulation in infertile patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Inclusion criteria: Women who are known as patients with poor response to ovulation stimulation according to POSEIDON 3 and 4 diagnostic criteria and will undergo the necessary treatment protocols for IVF/ICSI.
Exclusion criteria:
Azoospermia confirmed via a semen analysis History of surgery on the uterus Severe endometriosis through history and ultrasound findings Hydrosalpinx by ultrasound or hysterosalpingography Endocrine disorders such as diabetes, thyroid through blood biochemistry test Body Mass Index (BMI)>30 History of hysteroscopy History of recurrent abortions in the history History of recurrent failure of implantation (more than or equal to 3 times)
Age
From **15 years** old to **45 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **26**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committees of Research Ethics Committee of the "Alzahra Research Centers"
Street address
Hezar jarib Street
City
Esfahan
Province
Isfehan
Postal code
۷۳۴۶۱۸۱۷۴۶
Approval date
2022-09-11, 1401/06/20
Ethics committee reference number
IR.ARI.MUI.REC.1401.183

Health conditions studied

1

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

Primary outcomes

1

Description
The overall percentage of fertility in the proliferative phase and the luteal phase
Timepoint
Day 14 and day 28 after the start of ovarian stimulation
Method of measurement
optical microscope

Secondary outcomes

1

Description
The average number of metaphase 2 oocytes after ovulation in the proliferative phase and the luteal phase
Timepoint
Day 14 and day 28 after the start of ovarian stimulation
Method of measurement
optical microscope

2

Description
The average number of oocytes after ovulation in proliferative phase and luteal phase
Timepoint
Day 14 and day 28 after the start of ovarian stimulation
Method of measurement
optical microscope

3

Description
The average of number of 3-day-old embryos obtained after in vitro fertilization in the proliferative phase and the luteal phase
Timepoint

Day 17and day 31after the start of ovarian stimulation

Method of measurement

optical microscope

4

Description

The average quality of 3-day-old embryos obtained in proliferative phase and luteal phase

Timepoint

Day 17and day 31after the start of ovarian stimulation

Method of measurement

optical microscope

Intervention groups

1

Description

Intervention group: In the DuoStim method, ovarian stimulation is performed in both ovarian phases. From the third day of menstruation, all poor ovarian response patients who are candidates for in vitro fertilization undergo ovulation stimulation with gonadotropin at a dose of 300 units daily with Karma brand human gonadotropin (HMG) 150 units and Sinnal brand recombinant follicle stimulation hormone (FSH) 150 units. When the follicle diameter is higher than 14 mm, gonadotropin releasing hormone (GnRH) antagonist with Steronax brand 0.25 is used daily, and when at least two follicles with a diameter of 17 mm are seen through vaginal ultrasound with volusonE6 brand ultrasound machine, Ovitrol is used to trigger the oocyte of the patients. 250 single doses are used. Before transferring to the operating room for ovulation, polymerase chain reaction (PCR) test for COVID19 is requested from the couple, and if the corona test is negative, ovulation is performed. (Proliferative phase) On the same day, a sperm sample is taken from the wife and prepared by a laboratory process and microinjection is performed by an embryologist. Then, 3 days after ovulation, vaginal ultrasound is performed again to see the follicle, and the same drugs as mentioned (HMG and recombinant FSH and then GnRH antagonist) are started and continue with Ovitrol until the trigger time. Then ovulation is done (luteal phase) and on the same day, a sperm sample is taken from the wife and prepared by a laboratory process and microinjection is done by an embryologist.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Shahid Beheshti Hospital

Full name of responsible person

Safa Salehi

Street address

Metal Bridge - Ostad Motahari Street - Obstetrics and Gynecology Hospital - Shahid Beheshti Isfahan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Gholamreza Asghari

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Research and Technology Vice-Chancellor, Building No. 4, Isfahan University of Medical Sciences and Health Care Services, Hazar Jarib St.

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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

Esfahan University of Medical Sciences

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

Esfahan University of Medical Sciences

Full name of responsible person

Safa Salehi

Position

Non-faculty specialist doctor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for updating data

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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
Yes - There is 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
Title and more details about the data/document
-
When the data will become available and for how long
-
To whom data/document is available
-
Under which criteria data/document could be used
-
From where data/document is obtainable
-
What processes are involved for a request to access data/document
-
Comments