

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

+98 919 455 9022

Email address

mina.salehi123321@gmail.com

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

Isfahan

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 17 and day 31 after 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 17 and day 31 after 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

Street address

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

City

Esfahan

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8174673461

Phone

+98 31 3792 3060

Email

askari@mui.ac.ir

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

Street address

No. 2, Reyhan 6 Alley, Motahari St.

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Latest degree

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Other areas of specialty/work

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Person responsible for scientific 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

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Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Safa Salehi

Position

Non-faculty specialist doctor

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