Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Jun 2026

Compare the efficacy of two methods of Double Ovarian Stimulation for enhancing oocyte yield in assisted reproductive technology in patients with poor ovarian response

Protocol summary

Study aim

The efficacy of Double Ovarian Stimulation for enhancing oocyte yield in assisted reproductive technology in patients with poor ovarian response

Design

En Intervention group: In group A, first a course of contraceptive pills was given to patients and then on the first to third day of mensturation ultrasound was done and cinnafact was administered at a dose of 50 units for three days and on the third day Pergoverisis administered twice daily and only Pergoveris continued. Ultrasound is performed on the fifth day of ovulation stimulation to examine the size of the grown follicles. When one or two follicles reach a size of 18 mm, triggering was done with decapeptyl 0/2 Mg administered simultaneously with 10,000 units HCGa way that three to five days after the initial ovulation, the patient was given two ampoules of Pergoveris again when the size of the follicle reached 18 mm. Triggering was done by decaptil 0/2 mg and HCG 10000 units.

Settings and conduct

Patients with low respons ovarian reserve (poseidn 3,4) IVF and Infertility Center of Taleghani Hospital (Shahid Beheshti UNiversity).

Participants/Inclusion and exclusion criteria

Poor ovarian stimulation based on Poseidon group 3 criteria, AMH less than 1.2 ng / ml, antral follicle count less than 5 and age less than 35 years Group 4 poseidon includes older age equal to 35 years and AMH less than 1.2 ng/ml and the number of antral follicles less than 5 follicles. People with normal or excessive ovarian response will not be included in the study.

Intervention groups

Poor ovarian stimulation based on Poseidon group 3 criteria, AMH less than 1.2 ng / ml, antral follicle count less than 5 and age less than 35 years Group 4 poseidon includes older age equal to 35 years and AMH less than 1.2 ng/ml and the number of antral follicles less than 5 follicles.

Main outcome variables

Number of oocytes, number of embryos, number of blastocysts.

General information

Reason for update

Acronym

Duostim

IRCT registration information

IRCT registration number: **IRCT20200804048303N1**
Registration date: **2021-07-01, 1400/04/10**
Registration timing: **prospective**

Last update: **2021-07-01, 1400/04/10**
Update count: **0**

Registration date

2021-07-01, 1400/04/10

Registrant information

Name

Samaneh Sheibani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2223 9220

Email address

samane.sheibani@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-23, 1400/05/01

Expected recruitment end date

2021-09-21, 1400/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compare the efficacy of two methods of Double Ovarian Stimulation for enhancing oocyte yield in assisted reproductive technology in patients with poor ovarian response

Public title

The efficacy of Double Ovarian Stimulation for enhancing oocyte yield in assisted reproductive technology in patients with poor ovarian response

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Poor ovarian stimulation based on Poseidon group 3 criteria, AMH less than 1.2 ng / ml, antral follicle count less than 5 and age less than 35 years Group 4 poseidon includes older age equal to 35 years and AMH less than 1.2 ng/ml and the number of antral follicles less than 5 follicles Group 4 poseidon includes older age equal to 35 years and AMH less than 1.2 ng/ml and the number of antral follicles less than 5 follicles

Exclusion criteria:

Women with normal or excessive ovarian response
Women with excessive ovarian response

Age

No age limit

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **34**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

prospective interventional before and after study

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Preventative Gynecological Research Center

Street address

Taleqani Hospital , Shahid Arabi Ave, Yaman Ave, Shahid Chamran Highway , Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1985711151

Approval date

2021-01-31, 1399/11/12

Ethics committee reference number

IR.SBMU.RETECH.REC.1399.1079

Health conditions studied

1

Description of health condition studied

POOR OVERIAN RESPONSE

ICD-10 code

E28.9

ICD-10 code description

Ovarian dysfunction, unspecified

Primary outcomes

1

Description

Number of oocytes.

Timepoint

Compare the number of oocytes and MII oocytes after induction ovulation in the follicular and luteal phase and two methods flare stimulation and minimal stimulation,

Method of measurement

Ultrasonography and puncture of oocytes and evaluate the presence of a polar body.

2

Description

Number of embryos.

Timepoint

Number of embryos after induction ovulation and oocyte retrieval in follicular and luteal phase and compare two methods of flare stimulation and minimal stimulation.

Method of measurement

Inspection of embryos under the microscope.

3

Description

Number of blastocysts.

Timepoint

The number of blastocysts after oocyte retrieval in the follicular and luteal phases and compare the two methods of flare stimulation and minimal stimulation.

Method of measurement

Inspection of embryos under the microscope 5days after oocyte retrieval.

Secondary outcomes

1

Description

Clinical pregnancy

Timepoint

4-6 weeks after embryo transfer(ET)

Method of measurement

Transvaginal ultrasonography and observe existence of gestational sac and fetal heart rate

Intervention groups

1

Description

Intervention group: In group A, first a course of contraceptive pills was given to patients and then on the first to third day of mensturation ultrasound was done and cinnafact was administered at a dose of 50 units for three days and on the third day Pergoverisis administered twice daily and only Pergoveris continued. Ultrasound is performed on the fifth day of ovulation stimulation to examine the size of the grown follicles. When one or two follicles reach a size of 18 mm, triggering was done with decapeptyl 0/2 Mg administered simultaneously with 10,000 units HCGa way that three to five days after the initial ovulation, the patient was given two ampoules of Pergoveris again when the size of the follicle reached 18 mm. Triggering was done by decaptil 0/2 mg and HCG 10000 units.

Category

Treatment - Drugs

2

Description

Intervention group: In group B, after a course of contraceptive pills, on the first to third day of mensturation ultrasound was done, then letrozol 2/5 mg twice a day orally for five days from third day of menstration was started for patients wih injection of one pergoveris per day in 6th and 7th cycle- days. Follicular size was fallowed with transvaginal sonography When leading follicle was reached to 18mm 10,000 units HCG + 0/2 mg decapeptile was given intramuscularly. Then compared the results of the study between the two groups, including the number of oocytes recovered, the number of blastocysts found in the biopsy, the number of embryos transferred and the number of cases of successful clinical fertility.In the luteal phase, the GnRH antagonist will be considered.In such a way that three to five days after the initial ovulation, the patient was given two ampoules of Pergoveris again when the size of the follicle reached 18 mm. Triggering was done by decaptil 0/2 mg and HCG 10000 units.Then compared the results of the study between the two groups, including the number of oocytes recovered, the number of blastocysts found in the biopsy, the number of embryos transferred and the number of cases of successful clinical fertility.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani Hospial

Full name of responsible person

Samaneh Sheibani

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Taleghani hospital , Shahid Arabi Ave,Yaman Ave, Shahid Chamran highway , Tehran , Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr.Afshin Zarghi

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Taleghani Hospital, Shahid Arabi Ave, Yaman Ave, Shahid Chamran Highway, Teharan , Iran

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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
Shahid Beheshti University of Medical Sciences
Proportion provided by this source
50
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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Samaneh Sheibani
Position
Infertility fellowship resident
Latest degree
Specialist
Other areas of specialty/work
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Position
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Latest degree
Specialist
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Person responsible for updating data

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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
No - There is not a plan to make this available
Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

In this study, only part of the information about the main outcome can be shared.

When the data will become available and for how long

6month after published article.

To whom data/document is available

Researchers work at university and research parts.

Under which criteria data/document could be used

Analysis for scientific progression and improve treatment.

From where data/document is obtainable

Demand by e.mail to: S.sheibani.pgrc@gmail.com or refer to Taleghani Hospital IVF and Infertility ward.

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

We can e.mail data for at least one weak delay.

Comments