Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of Dual Stimulation In Vitro Fertilization(IVF)-Intra Cytoplasmic Sperm Injection (ICSI) in one cycle with IVF-ICSI in two separate cycles in Poor Responder Patients

Protocol summary

Study aim

Comparison of Dual Stimulation IVF-ICSI in one cycle with IVF-ICSI in two separate cycles in Poor Responder Patients

Design

This study is a clinical trial with a control group with parallel and unblinded groups, and the patients will be divided into two intervention and control groups using the random block randomization method. The study phase will be 2 and the sample size will be 40 patients.

Settings and conduct

in this clinical trial study infertile women with primary infertility and the criteria of poor ovarian response who refer to the infertility ward of Al-Zahra Hospital in TABRIZ for IVF-ICSI are identified and patients are divided into two groups. in case group patient will be treated with IVF protocol two time in a cycle (in follicular and luteal phase). in control group patient will be treated in two separated cycle to achieve more follicles.The study is not blinded.

Participants/Inclusion and exclusion criteria

Patients between 20 and 42 years of age and primary infertility will be included in the study, and in case of severe oligospermia of the husband or severe endometriosis, they will be prohibited from entering the study.

Intervention groups

After the follicles reach a size of 17 mm or more, administration (10,000 units of HCG) will be administered and 34 to 36 hours later, oocyte recovery will be done.In the patients of the intervention group (Duostim), three days later,a repeat visit will be performed and a new cycle of IVF-ICSI will start, similar to the cycle of follicular phase treatment.

Main outcome variables

Rate of fertilization

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130603013566N12**
Registration date: **2023-04-11, 1402/01/22**
Registration timing: **prospective**

Last update: **2023-04-11, 1402/01/22**
Update count: **0**

Registration date

2023-04-11, 1402/01/22

Registrant information

Name
Kobra Hamdi

Name of organization / entity
Tabriz University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-13, 1402/01/24

Expected recruitment end date

2024-04-12, 1403/01/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of Dual Stimulation In Vitro Fertilization(IVF)-Intra Cytoplasmic Sperm Injection (ICSI) in one cycle with IVF-ICSI in two separate cycles in Poor Responder Patients

Public title
Comparing the results of ovulation stimulationDouble or dual stimulation in poor ovarian responders

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
The patients with first type of infertility Age 20 to 42 years
Exclusion criteria:
Severe oligospermia BMI is 30 or higher Severe endometriosis Concomitant chronic disease Smoking and alcohol consumption

Age
From **20 years** old to **42 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization method used in this study is the use of a table of random numbers.Random number table is a set of numbers that is generated without a specific pattern or order and they generated randomly and they are formed in a table.In first the direction of reading the numbers was specified.To read the numbers, random numbers are read from the left side of the table, then even numbers extracted from the table are allocated to intervention group and odd numbers extracted from the table are allocated to intervention control group.

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 Tabriz University Of Medical Sciences

Street address
Third Floor; Central Building of Number2; Golgasht Street

City
Tabriz

Province
East Azarbaijan

Postal code
5166616471

Approval date
2023-02-20, 1401/12/01

Ethics committee reference number
IR.TBZMED.REC.1401.1073

Health conditions studied

1

Description of health condition studied
Infertility

ICD-10 code
N97.0

ICD-10 code description
Female infertility associated with anovulation

Primary outcomes

1

Description
Number of resulted oocytes

Timepoint
The day of oocytes pick up

Method of measurement
Microscopic evaluation

2

Description
Quality of resulted oocytes

Timepoint
The day of oocytes pick up

Method of measurement
Microscopic evaluation

3

Description
Dosage of Follicle-stimulating hormone.(FSH)

Timepoint
From day 2 until the time of injection

Method of measurement
Number of follicle stimulating (FSH) hormone ampoules

4

Description
Dosage of Generic human menopausal gonadotropin (hMG)

Timepoint
From day 2 until the time of injection
Method of measurement
Number of Generic human menopausal gonadotropin (hMG)

Secondary outcomes

1

Description
Implantation rate
Timepoint
4-6 weeks after embryos transfer (ET)
Method of measurement
Vaginal sonography

2

Description
Ongoing pregnancy rate
Timepoint
Pregnancy after 12 weeks of gestation
Method of measurement
Ultrasound

Intervention groups

1

Description
Intervention group: The time interval from the previous In Vitro Fertilization(IVF)-Intra Cytoplasmic Sperm Injection (ICSI) will be at least 2-3 months. And during this period, patients will receive auxiliary treatment including one daily zinc tablet, Dehydroepiandrosterone capsule with a dose of 100 mg daily, vitamin D and folic acid.From the 2nd day of the menstrual cycle, after performing an ultrasound and not seeing an ovarian cyst or follicle above 13 mm, letrozole 2.5 mg tablets will be taken twice every night, and from the 3rd or 4th day of the period,Follicle-Stimulating Hormone(FSH) ampoules (signal F_) with a dose 225 daily units will start, from the 6th day of menstruation, 1-2 HMG KARMA ampoules (75 to 150) units will be added to the treatment regimen. 5-6 days after the start of gonadotropins, patients will be visited and transvaginal ultrasound will be done.Based on the size of the follicles in the transvaginal ultrasound, the treatment with gonadotropin will continue and if needed, the dose of gonadotropin will be increased up to a maximum of 300 units of FSH and a maximum of 150 units of Human chorionic gonadotropin (hCG) HMG.When the follicle size reaches 13-14 mm, GnRH antagonist (Stronax - Cinagen 250 micrograms) will be added to the treatment regimen. In the future, patients will be visited every two days. After the follicles reach a size of 17 mm or more, administration (10,000 units of HCG) will be administered and 34 to 36 hours later, oocyte recovery will be done.In the patients of the intervention group (Duostim), three days later, i.e. in the luteal phase, a repeat visit will be performed and a new cycle of IVF-ICSI will start, similar to the cycle of follicular phase treatment. If a hemorrhagic cyst is observed in the ovary, caused by previous ovulation, the patients will be excluded from the study group and new ovulation stimulation will not start.
Category
Treatment - Drugs

2

Description
Control group: The time interval from the previous In Vitro Fertilization(IVF)-Intra Cytoplasmic Sperm Injection (ICSI) will be at least 2-3 months. And during this period, patients will receive auxiliary treatment including one daily zinc tablet, Dehydroepiandrosterone capsule with a dose of 100 mg daily, vitamin D and folic acid.From the 2nd day of the menstrual cycle, after performing an ultrasound and not seeing an ovarian cyst or follicle above 13 mm, letrozole 2.5 mg tablets will be taken twice every night, and from the 3rd or 4th day of the period,Follicle-Stimulating Hormone(FSH) ampoules (signal F_) with a dose 225 daily units will start, from the 6th day of menstruation, 1-2 HMG KARMA ampoules (75 to 150) units will be added to the treatment regimen. 5-6 days after the start of gonadotropins, patients will be visited and transvaginal ultrasound will be done.Based on the size of the follicles in the transvaginal ultrasound, the treatment with gonadotropin will continue and if needed, the dose of gonadotropin will be increased up to a maximum of 300 units of FSH and a maximum of 150 units of Human chorionic gonadotropin (hCG) HMG.When the follicle size reaches 13-14 mm, GnRH antagonist (Stronax - Cinagen 250 micrograms) will be added to the treatment regimen. In the future, patients will be visited every two days. After the follicles reach a size of 17 mm or more, administration (10,000 units of HCG) will be administered and 34 to 36 hours later, oocyte recovery will be done.In the patients of the control group, IVF-ICSI will be started again, according to the usual procedure of the infertility department, at least 1-2 months after the start of the menstrual cycle.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for Research,Tabriz University Of Medical Sciences
Full name of responsible person
Dr.Mohammad Samiei
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No. 2 Central Building,Tabriz University of Medical Sciences, Golgasht Street, Tabriz
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research-vice@tbzmed.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for Research,Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Kobra Hamdi
Position
Associate Professor of Obstetrics Gynecology
Latest degree
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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