

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Evaluation of IVF Outcomes in Patients with Decreased Ovarian reserve with Double Stimulation during Follicular and Luteal Phase Compared with conventional Antagonist Cycle

Protocol summary

Study aim

Evaluation of IVF Outcomes in Patients with Decreased Ovarian reserve with Double Stimulation during Follicular and Luteal Phase Compared with conventional Antagonist Cycle

Design

Two arm parallel group randomised, single blinded clinical trial with 54 patients. For randomization, permutation block stratified randomization method was used.

Settings and conduct

This randomized study will be performed on 54 women IVF candidates in the infertility center of Ali Ibn Abitaleb Hospital in Zahedan. patients will be divided into the two intervention groups. The data collection tool is through a data collection checklist. In this single-blinded clinical trial without control group, randomization will be performed by permutation block method.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with reduced ovarian reserve who are candidates for IVF. Endometriosis less than grade 3. No contraindications to use of ovarian stimulation medications. At the same time, the patient's partner should not have azoospermia.

Intervention groups

Intervention group: Double Stimulation Intervention group: conventional Antagonist Cycle

Main outcome variables

Total oocyte recovery rate The mean Metaphase II (MII) oocyte counts The number of fetus

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120817010617N8**

Registration date: **2021-07-21, 1400/04/30**

Registration timing: **registered_while_recruiting**

Last update: **2021-07-21, 1400/04/30**

Update count: **0**

Registration date

2021-07-21, 1400/04/30

Registrant information

Name

morteza Sedaghat Kia

Name of organization / entity

zaums

Country

Iran (Islamic Republic of)

Phone

+98 54 1244 9540

Email address

morimedico@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-11, 1400/04/20

Expected recruitment end date

2022-01-10, 1400/10/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of IVF Outcomes in Patients with Decreased Ovarian reserve with Double Stimulation during Follicular and Luteal Phase Compared with conventional

Antagonist Cycle	
Public title	Evaluation of IVF Outcomes in Patients with Decreased Ovarian reserve with Double Stimulation Compared with conventional Antagonist Cycle
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: Patients with reduced ovarian reserve who are candidates for IVF. Endometriosis less than grade 3. No contraindications to use of ovarian stimulation medications. At the same time, the patient's partner should not have azoospermia. Exclusion criteria:
Age	To 40 years old
Gender	Female
Phase	2-3
Groups that have been masked	Care provider
Sample size	Target sample size: 54
Randomization (investigator's opinion)	Randomized
Randomization description	Random assignment of patients to two groups will be done by permutation block stratified randomization method. Eligible patients will be classified according to age and BMI, respectively. Then, based on 4 blocks (consisting of two groups A and B and two repetitions for each) patients will be randomly selected from all possible modes of permutations, and will be assigned to the desired group.
Blinding (investigator's opinion)	Single blinded
Blinding description	In this clinical trial, the Single-Blinding method will be used. So that the technician responsible for recording of the consequences will not be aware of the intervention.
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	Ethics Committee of Zahedan University of Medical Sciences

Street address	Dr.Hesabi Square
City	Zahedan
Province	Sistan-va-Balouchestan
Postal code	9816743463
Approval date	2021-01-10, 1399/10/21
Ethics committee reference number	IR.ZAUMS.REC.1399.447
Health conditions studied	
<u>1</u>	
Description of health condition studied	Infertility
ICD-10 code	N97
ICD-10 code description	Female infertility
Primary outcomes	
<u>1</u>	
Description	Total oocyte recovery rate
Timepoint	After oocyte retrieval
Method of measurement	Via Ultrasound Sonography
<u>2</u>	
Description	The mean Metaphase II (MII) oocyte counts
Timepoint	Oocyte pick up day
Method of measurement	Microscopic assay
<u>3</u>	
Description	The number of fetus
Timepoint	After puncture
Method of measurement	Microscopic assay -The number of fetuses after injection.
Secondary outcomes	empty
Intervention groups	
<u>1</u>	
Description	

Intervention group: Double Stimulation, Patient's receipt HMG and FSH from day 2 and then when the follicle is upper 13-millimeter cetrotide is consumed and when the follicle is upper 18 mliletr HCG is injected and after 36 hours puncture of the follicles is done. From the day after the puncture, patients receive one steroid antagonist daily for 4 days to lower hormone levels.

Category

Treatment - Drugs

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Description

Intervention group: conventional Antagonist Cycle, Patients receipt cetrotide for three days that started from day 2 and after that HMG and FSH is started and then when the follicle is upper 13-millimeter cetrotide is consumed and when the follicle is upper 18 mliletr HCG is injected and after 36 hours puncture of the follicles is done.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali-ebn Abi Taleb Hospital, Zahedan

Full name of responsible person

Fateme Qahqaei

Street address

Ali-ebn Abi Talib Hospital, Salamat boulevard,
Dr.Hesabi square ,Zahedan

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743111

Phone

+98 54 3329 5570

Email

morimedico@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Dr. Nour Mohammad Bakhshani

Street address

Dr Hesabi square

City

zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Phone

+98 54 3329 5744

Email

zaums.research@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Zahedan 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

Zahedan University of Medical Sciences

Full name of responsible person

Fateme Qahqaei

Position

Obstetrics & Gynecology Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

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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