

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Comparison of the effect of metformin and the combination of acid folic and myo-inositol in infertility patients with poly cystic ovary syndrom (PCOS) who undergoing IVF for the test time.

Protocol summary

Study aim

-Comparison on the BMI -Comparison on the fertilization rate -Comparison on the ovum count-Comparison on the ovum quality-Comparison on the embryo count - Comparison on the embryo quality -Comparison follicle count-Comparison on the follicle size -Comparison on the EP rate-Comparison on the abortion rate-Comparison on the OHSS rate

Design

two arm parallel group randomized trial with double bind , phase 3 on 140 patient

Settings and conduct

After patients entered the study and obtained informed consent in the infertility clinic of Yas Hospital and recorded demographic information including age, weight, height, body mass index, duration of infertility, type of infertility, history of abortion and EP and random drug selection by infertility resident and starting from three month before IVF cycle until ovum puncture,the size and count of follicles recorded by trans vaginal ultrasound .then performed IVF in IVF operating room of Yas Hospital.patients followed for pregnancy by beta HCG and ultrasound,as well as for abortion and EP. OHSS were carefully monitored for event during the cycle. In this study, the drug was prescribed by a resident of the infertility clinic after random selection and the researcher and the statistical unit did not interfere in this process and were not aware and blinding was performed

Participants/Inclusion and exclusion criteria

Infertile women with PCOS who were scheduled to undergoing IVF and had no other cause of infertility.

Intervention groups

Control group: Consumers of metformin as an old and common drug Intervention group: Consumers of a new drug combining myo-inosito and acid folic

Main outcome variables

BMI, ovum count, ovum quality, embryo count, embryo

quality, follicle size, follicle count, fertilization rate, abortion rate, EP rate, OHSS rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201219049758N1**

Registration date: **2021-01-02, 1399/10/13**

Registration timing: **retrospective**

Last update: **2021-01-02, 1399/10/13**

Update count: **0**

Registration date

2021-01-02, 1399/10/13

Registrant information

Name

Fereshteh Rastegar

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 4403 4589

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-08-23, 1397/06/01

Expected recruitment end date

2019-08-23, 1398/06/01

Actual recruitment start date

2018-10-02, 1397/07/10

Actual recruitment end date

2020-02-09, 1398/11/20

Trial completion date

2020-06-17, 1399/03/28

Scientific title

Comparison of the effect of metformin and the combination of acid folic and myo-inositol in infertility patients with poly cystic ovary syndrom (PCOS) who undergoing IVF for the test time.

Public title

Comparison effect of Metformin and combination of acid folic and myo-inositol" in poly cystic ovary syndrome"

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

First IVF No history of ovarian manipulation Lack of male infertility factor Patency of fallopian tubes No history of smoking

Exclusion criteria:

History of IVF history of ovarian manipulation male infertility factor No patency of fallopian tubes history of smoking

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **140**

Actual sample size reached: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

Random allocation rule:First, 70 letters A and 70 letters B were written on special papers that were not marked inside. Then all of them were placed in a bag and for each patient, after obtaining informed consent, a paper was removed randomly and without replacement, and based on the letter written on it, the desired intervention was performed for the patient. In addition, interventions A or B were determined by a lot.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is performed as double-blind, the researcher and the analyzer do not know the type of treatment. The drug is used by the infertility resident physician for the patient after random selection.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Tehran University of Medical Sciences

Street address

Deputy of research , First floor, Building number 1, Faculty of Medicine, Norethern entrance of Tehran University of Medical Science, Poursina Street, Qods Street, Enghelab Street

City

Tehran

Province

Tehran

Postal code

1598718311

Approval date

2020-11-18, 1399/08/28

Ethics committee reference number

IR.TUMS. MEDICIN. REC.1399.766

Health conditions studied

1

Description of health condition studied

Infertility, Polycystic ovary syndrome

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Improving fertility in patients with polycystic ovary syndrome

Timepoint

Before starting the drug from three months before the start of the IVF cycle until the puncture and then before the puncture then comparison of two drug in fertilization rate

Method of measurement

HCG, Ultrasound

Secondary outcomes

1

Description

Body Mass Index, Fertilization rate, Abortion rate, EP rate, OHSS rate, Ovum count, Ovum quality, Embryo count, , Embryo quality, Follicle count,Follicle size

Timepoint

Patients took the drug three months before the start of

the IVF cycle until the puncture, Body Mass Index was measured before and after the drug was completed.

Method of measurement

Body Mass Index: weight(kg) on height(cm²), Fertility: HCG and ultrasound, Abortion: HCG and ultrasound, EP: HCG and ultrasound, OHSS: ultrasound, Follicle size: ultrasound, Follicle count: ultrasound, ovum count: microscopic and embryologist, ovum quality: microscopic and embryologist, Embryo count: microscopic and embryologist, Embryo quality: microscopic and embryologist

Intervention groups

1

Description

Intervention group: Received combination of 2000 mg and 200 micro gr Folic acid twice a day

Category

Treatment - Drugs

2

Description

Control group: Received 500 mg three time a day

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Yas Hospital

Full name of responsible person

zahra rezaee

Street address

Yas Hospital, Next to the sarv street, Northern Nejatollahi Street, Karim khan Aven

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Fereshteh rastegar

Position

Specialist

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)

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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

All data is potentially shareable after unidentified participant

When the data will become available and for how long

After manuscript published

To whom data/document is available

No limitations

Under which criteria data/document could be used

The data is only available to the project manager, Dr.Rezaee and my analysis done with must be done with her opinion .

From where data/document is obtainable

Dr. Zahra rezee

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

Any regeust must be made in writing and accompanied by a proposal with an ethics code under the supervision of Dr. Rezee

Comments