

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jun 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 blind , 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)

##### Phone

+98 21 4403 4589

##### Email address

rastegasr.freshteh@gmail.com

##### 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 fallupian tubes No history of smoking

#### Exclusion criteria:

History of IVF history of ovarian manipulation male infertility factor No patency of fallupian 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 Streat, 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(cm<sup>2</sup>), 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

###### **City**

Tehran

###### **Province**

Tehran

###### **Postal code**

1598718311

###### **Phone**

+98 21 8608 9089

###### **Email**

zhrrrezaee@yahoo.com

### **Sponsors / Funding sources**

#### **1**

##### **Sponsor**

###### **Name of organization / entity**

Tehran University of Medical Sciences

###### **Full name of responsible person**

Zahra Rezaee

###### **Street address**

Yas Hospital, Next to the sarve street, Northern Nejatollahi street, karim Khan Aven

###### **City**

Tehran

###### **Province**

Tehran

###### **Postal code**

1597856511

###### **Phone**

+98 21 8608 9089

###### **Email**

zhrrrezaee@yahoo.com

##### **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

###### **Street address**

No.10, Yas street., Northern Vafa azar Aven, West Ferdows Blvn,

###### **City**

Tehran

###### **Province**

Tehran

###### **Postal code**

1481863373

###### **Phone**

+98 21 4403 4589

###### **Email**

rastegar.freshteh@gmail.com

### **Person responsible for scientific inquiries**

##### **Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Zahra rezee

**Position**

Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

Yas Hospital, Next to the sarv street, Northern  
Nejatollahi Karimkhan

**City**

Tehran

**Province**

Tehran

**Postal code**

1597856511

**Phone**

+98 21 8608 9089

**Email**

zhrrzee@yahoo.com

Tehran

**Postal code**

1598718311

**Phone**

009898718311

**Email**

elhamfeizabad@gmail.com

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

**Comments****Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Elham Feizabad

**Position**

Spccialist

**Latest degree**

Specialist

**Other areas of specialty/work**

Public Health/Community Medicine

**Street address**

Yas Hospital, Next to the sarv street, Northern  
Nejatollahi, Karimkhan Aven

**City**

Tehran

**Province**