Comparison of the effect of metformin and the combination of acid folic and myo-inositol in infertility patients with poly cystic ovary syndrome (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-inositol 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
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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
**Scientific title**

Comparison of the effect of metformin and the combination of acid folic and myo-inositol in infertility patients with poly cystic ovary syndrome (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, Northerm entrance of Tehran University of Medical Science, Poursina Streart, 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

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 sarve street, Northern Nejatollahi street, karim khan Aven
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Email
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Sponsors / Funding sources

1
Sponsor
Name of organization / entity
Tehran University of Medical Sciences
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Person responsible for general inquiries

Contact
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Fereshteh rastegar
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Specialist
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for updating data

Contact

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Full name of responsible person
Elham Feizabad

Position
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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 reze

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