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 ovum count
- Comparison on the ovum quality
- Comparison on the embryo count
- Comparison on the embryo quality
- Comparison on the 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-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
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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 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 histoty of ovarian manipulation Lack of male infertility factor Patency of fallopian tubes No history of smoking

Exclusion criteria:
History of IVF histoty 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, Pourisina 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**: ultrasound.
- **OHSS**: ultrasound.
- **Follicle size**: ultrasound.
- **Follicle count**: ultrasound, ovum count:
- **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 sarve street, Northern Nejatollahi street, karim khan Aven

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

Comments