Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jun 2026

Effect of myo-inositol on the expression of survivin and caspase 3&7 genes in granulosa cells and the level of biochemical factors of follicular fluid and its relation on oocytes and embryos quality in patients with PCOs undergoing ICSI treatment

Protocol summary

Study aim
The effect of myoinositol supplementation on the expression of survivin and caspase 3 and 7 genes in granulosa cells and follicular fluid biochemical factors and its relationship with the quality of eggs and embryos obtained in patients with polycystic ovary syndrome (PCOs) undergoing Intra Cytoplasmic Sperm Injection (ICSI) treatment

Design
It is a prospective, randomized, placebo-controlled clinical trial study among infertile female patients with PCOS.Group 1: 30 patients were treated with folic acid 1 mg and myoinositol 2000 mg twice a day for 6 weeks. Group 2: 30 patients as a control group who take folic acid 1 mg.

Settings and conduct
The patients were selected and sampled from among the clients to Jihad Qom Infertility Treatment Center, and after undergoing tests, they entered the ICSI stage, and the quality of the resulting eggs and embryos and their biochemical information were analyzed

Participants/Inclusion and exclusion criteria
Entry conditions: having at least two indicators from the Rotterdam indices and exit conditions: male factor infertility, Cushing's syndrome, congenital adrenal hyperplasia, hyperprolactinemia, thyroid disorders, pelvic organ pathology, androgen secretion neoplasia, diabetes mellitus

Intervention groups
A study was conducted on 60 infertile patients suffering from PCOS in order to investigate the effect of inositol on the quality of eggs and embryos obtained from these patients. In group B, only 1 mg of acidofolid was prescribed daily

Main outcome variables
Evaluation gene expression: survivin, caspase 3and 7

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220921056008N1**
Registration date: **2022-10-19, 1401/07/27**
Registration timing: **registered_while_recruiting**

Last update: **2022-10-19, 1401/07/27**
Update count: **0**

Registration date
2022-10-19, 1401/07/27

Registrant information

Name
Zeynab Yazdanpanah

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-05-22, 1401/03/01

Expected recruitment end date
2022-10-23, 1401/08/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Effect of myo-inositol on the expression of survivin and caspase 3&7 genes in granulosa cells and the level of biochemical factors of follicular fluid and its relation on oocytes and embryos quality in patients with PCOs undergoing ICSI treatment

Public title
Effect of myo-inositol on PCOS

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
PCOS diagnostic criteria based on the Rotterdam consensus

Exclusion criteria:
Male factor infertility. Cushing syndrome. Congenital adrenal hyperplasia. Thyroid dysfunction, hyperprolactinemia, androgen secretion neoplasia, diabetes mellitus

Age
From **20 years** old to **40 years** old

Gender
Female

Phase
2-3

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
In order to avoid biased answers, PCOS patients were divided into two groups with equal numbers by a simple random method in such a way that 60 beads are placed in a box numbered from 1 to 60 and from each number There are 1 beads in the box. After accepting each patient and after obtaining informed consent, the treating doctor randomly removes one of the beads inside the box (without seeing the contents of the box) and in this way the people are classified into different groups, so that Odd numbers belong to the first intervention group (Inositol) and even numbers belong to the second intervention group (Acidfolic).

Blinding (investigator's opinion)
Double blinded

Blinding description
The type of research is double-blind and only the researcher knows how to group the patients. The type of drug regimen is presented to the patient by the doctor, but both the doctor and the patient are not in the process of dividing the research intervention groups, and only the researcher is in the process of dividing the patients in It is groups. The method of blinding will be in such a way that the patient is unaware of the type of treatment he will receive and the control group will receive a placebo. After dividing the participants into experimental groups and the control group, the method of performing the exercises and the exact duration of the exercises will be explained to the volunteers to participate in the research. They declare themselves to participate in the research. The conditions for entering the exam include having at least one year of infertility due to female causes (polycystic ovary syndrome) and being in good health in terms of other diseases

Placebo
Used

Assignment
Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Islamic Azad University, Varamin-Pishva branch

Street address
Islamic Azad University, Parand branch.Parand city - Bahonar boulevard .Kilometer 32 of Tehran Saveh highway.

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Approval date
2021-08-31, 1400/06/09

Ethics committee reference number
IR.IAU.VARAMIN.REC.1400.033

Health conditions studied

1

Description of health condition studied
Polycystic ovary syndrome

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
The level of gene expression of caspase 3 and 7 and survivin

Timepoint
After ovarian puncture

Method of measurement
Real time PCR

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:This group includes 30 patients with polycystic ovary syndrome who were candidates for infertility treatment with ICSI according to the opinion of the gynecologist. These patients received 2000 mg of inositol daily during the ICSI (implantation) cycle for three weeks (FairhavenHealth- (IRAN company) along with 1 mg of folic acid (Raha-Iran company). Then, after ovarian puncture, follicular fluid and granulosa cells and eggs are checked in terms of chemical and chemical parameters

Category

Treatment - Drugs

2

Description

Control group: This group includes 30 patients with polycystic ovary syndrome who are candidates for infertility treatment with ICSI according to the opinion of the gynecologist. During the ICSI (embryo implantation) cycle, these patients receive one milligram of folic acid daily (Reha company) for three weeks. -Iran) are consumed, then after ovarian puncture, follicular fluid and granulosa cells and other biochemical and hormonal parameters as well as the quality of eggs are checked

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Qom Academic Jihad Infertility Treatment Center

Full name of responsible person
Zeynab Yazdanpanah

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Sponsors / Funding sources

1

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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
Islamic Azad University

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
Islamic Azad University

Full name of responsible person
Zeynab Yazdanpanah

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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
Yes - There is a plan to make this available
Title and more details about the data/document
All information related to potential data can be shared after de-identifying individuals
When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available
Researchers working in universities and scientific institutions
Under which criteria data/document could be used
Provide a relevant university degree
From where data/document is obtainable
z_yazdanpanah68@yahoo.com
What processes are involved for a request to access data/document
After receiving the request via email, the data will be sent within a week
Comments