

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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 3 and 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)

Phone

+98 25 3760 8379

Email address

zyazdanpanah@piaou.ac.ir

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		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	
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	Placebo	Used
Public title	Effect of myo-inositol on PCOS	Assignment	Other
Purpose	Treatment	Other design features	
Inclusion/Exclusion criteria		Secondary Ids	empty
Inclusion criteria:	PCOS diagnostic criteria based on the Rotterdam consensus	Ethics committees	
Exclusion criteria:	Male factor infertility. Cushing syndrome. Congenital adrenal hyperplasia. Thyroid dysfunction, hyperprolactinemia, androgen secretion neoplasia, diabetes mellitus	1	
Age	From 20 years old to 40 years old	Ethics committee	
Gender	Female	Name of ethics committee	Ethics Committee of Islamic Azad University, Varamin-Pishva branch
Phase	2-3	Street address	Islamic Azad University, Parand branch.Parand city - Bahonar boulevard .Kilometer 32 of Tehran Saveh highway.
Groups that have been masked	• Participant • Care provider	City	Parand
Sample size	Target sample size: 60	Province	Tehran
Randomization (investigator's opinion)	Randomized	Postal code	۳۷۶۱۳۹۶۳۶۱
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).	Approval date	2021-08-31, 1400/06/09
Blinding (investigator's opinion)	Double blinded	Ethics committee reference number	IR.IAU.VARAMIN.REC.1400.033
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	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

Street address

Jihad Academic Infertility Treatment Center, Qom Province Branch. Ithar Square. Royan Square. Shahid Karimi Blvd Shahid Haqqani St.

City

Qom

Province

Ghorm

Postal code

۳۷۱۶۹۸۶۴۶۶

Phone

+98 25 3285 9856

Email

rooyaivfacecrqom@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Mitra Heydari Nasrabadi

Street address

Islamic Azad University, Parand branch. Bahonar Blvd. Parand city. Kilometer 32 of Tehran Saveh highway

City

Parand

Province

Tehran

Postal code

۳۷۶۱۳۹۶۳۶۱

Phone

+98 21 5673 3001

Email

info@piaa.ac.ir

Web page address

<https://parand.iau.ir/>

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

Position

PHD student

Latest degree

Master

Other areas of specialty/work

Biology

Street address

Zomorrod building. Alley 52. 19th Street

City

Qom

Province

Ghorm

Postal code
۳۷۱۳۶۵۹۴۳۷
Phone
+98 25 3760 8379
Email
zyazdanpanah@piaou.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Islamic Azad University
Full name of responsible person
Mitra Heydari Nasrabadi
Position
Associate Professor
Latest degree
Ph.D.
Other areas of specialty/work
Others
Street address
Islamic Azad University, Parand branch. Bahonar
Blvd.Parand city.Kilometer 32 of Tehran Saveh
highway
City
Parand
Province
Tehran
Postal code
۳۷۶۱۳۹۶۳۶۱
Phone
+98 21 5673 3001
Email
heydarimitra45@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Islamic Azad University
Full name of responsible person
Zeynab Yazdanpanah
Position
PHD student
Latest degree
Master
Other areas of specialty/work

Others
Street address
Zomorrod building. Alley 52. 19th Street
City
Qom
Province
Ghoum
Postal code
۳۷۱۳۶۵۹۴۳۷
Phone
+98 25 3760 8379
Email
zyazdanpanah@piaou.ac.ir

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