

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Sep 2026

Comparison of the effect of Sitagliptin and Inositol on the Oocyte and Embryo Quality in Poly Cystic Ovarian Syndrome (PCOS) Patients Undergoing Intra Cytoplasmic Sperm Injection (ICSI)

Protocol summary

Study aim

Comparison of Mean Levels of Testosterone, Cholesterol, Triglyceride, Oocyte Quality, Embryo Quality, BMI, LH, FSH in Two Groups Treated with Inositol and Sitagliptin Addition to Inositol

Design

The Clinical Trial, One Control Group with a Parallel Group, double Blind, Randomized, Phase 3 on 70 Patients who will be Randomized with Block Method

Settings and conduct

Body Mass Index and Levels of Fasting Blood Sugar, Luteinizing Hormone & Follicle-Stimulation Hormone, Triglyceride, Cholesterol and Testosterone are Evaluated Before Starting in Both Groups. Group A will Receive their Routine Medications Plus Sitagliptin Tablet and Inofolic Powder, and Group B will Receive their Routine Medications Plus Inofolic Powder, 8 Weeks Before the Start of In Vitro Fertilization Cycle in the Infertility Center of Shahid Beheshti Hospital in Kashan, and then Embryo Transfer will be Done with Appropriate Quality. The Quality of Embryo and Oocyte and Laboratory Criteria and Body Mass Index will be Investigated in Two Groups

Participants/Inclusion and exclusion criteria

Inclusion Criteria People with Polycystic Ovarian Syndrome, Age Between 18 and 40 Years Old, Known Case of Polycystic Ovarian Syndrome, and Based on their Infertility Records, are Candidates for Entering the Cycle of Infertility Treatment and ICSI; Exclusion Criteria People with Uterine Abnormalities

Intervention groups

Group Treated with Inositol Group Treated with Inositol and Sitagliptin

Main outcome variables

Embryo Quality, Oocyte Quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240128060827N1**

Registration date: **2024-02-11, 1402/11/22**

Registration timing: **prospective**

Last update: **2024-02-11, 1402/11/22**

Update count: **0**

Registration date

2024-02-11, 1402/11/22

Registrant information

Name

Mahdis Rajabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 5500 5363

Email address

mahdiis174@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-04-02, 1403/01/14

Expected recruitment end date

2024-06-03, 1403/03/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Sitagliptin and Inositol on the Oocyte and Embryo Quality in Poly Cystic Ovarian Syndrome (PCOS) Patients Undergoing Intra Cytoplasmic Sperm Injection (ICSI)

Public title

Comparison the Effect of Sitagliptin and Inositol on the Fertility Treatment in Polycystic Ovarian Syndrome

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

People with Polycystic Ovarian Syndrome Age Between 18 and 40 Years People who are Known Case of Polycystic Ovarian Syndrome Based on Sonographic and Laboratory Findings Contained in the Case file People who are Candidates for Infertility Treatment and ICSI Based on Infertility Records

Exclusion criteria:

People with Uterine Abnormalities (such as Asherman's Syndrome, Fibroids, Polyps, and a Diagnosis of Adenomyosis) Contraindications for Inositol and Sitagliptin Treatment Cycles with Embryo Donation or Prenatal Genetic Screening Endometriosis and Infertility with Unknown Cause Severe Male Factor Infertility

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

First, the Drug Package of Sitagliptin and Inofolic was Coded with the Letter A and the Drug Package of Inofolic with the Letter B, and then using the Website www.sealdenvelope.com/simple-randomiser/v1/lists, the Randomization List was Selected by Selecting a Sample Size of 70. And it is Prepared by Balanced Quadruple Blocking Method. Then, through the obtained Randomization list, the People Included in the study will be Assigned to one of the two groups A and B. For example, suppose that in the first quartet block, the permutation method is ABBA, so the first and fourth samples will be assigned to group A and the second and third samples will be assigned to group B, and it will continue in this way until the last sample

Blinding (investigator's opinion)

Single blinded

Blinding description

A person who has no Role in this Trial and is not Aware of

the Random Allocation will Allocate the Drugs to the Participants, a code will be Placed on the box of the Drugs. The Researcher is Unaware of the Type of Intervention and After Analyzing the Data, the Package Codes will be Decoded. Considering that the Form of Drugs and their Consumption are not the same, one is in the form of Powder and the other is a Tablet, and Considering the Proven Therapeutic Effect of Inofolic Powder in the Treatment of Infertility, Placebo cannot be Considered.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Kashan University of Medical Sciences

Street address

Ghotbe Ravandi blv, Kashan Medical Science University

City

Kashan

Province

Isfahan

Postal code

8814187159

Approval date

2023-12-11, 1402/09/20

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1402.225

Health conditions studied**1****Description of health condition studied**

Polycystic Ovarian Syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

Primary outcomes**1****Description**

Oocyte Quality

Timepoint

8 Weeks Later Use of Medications

Method of measurement

Microscope

2

Description

Embryo Quality

Timepoint

8 Weeks Later Use of Medications

Method of measurement

Microscope

Secondary outcomes

1

Description

Body Mass Index

Timepoint

At the beginning of the study and 8 weeks later

Method of measurement

Dividing Weight by Height to the Power of 2

2

Description

Luteinizing hormone

Timepoint

At the beginning of the study and 8 weeks later

Method of measurement

ELISA test

3

Description

Follicle stimulating hormone

Timepoint

At the beginning of the study and 8 weeks later

Method of measurement

ELISA test

4

Description

Fasting Blood Sugar

Timepoint

At the beginning of the study and 8 weeks later

Method of measurement

ELISA test

5

Description

Testosterone

Timepoint

At the beginning of the study and 8 weeks later

Method of measurement

ELISA test

Intervention groups

1

Description

Intervention group: Patients in the Intervention Group Received Sitagliptin Tablets 50 mg Every 12 Hours Made by Abidi Company and Inofolic Powder Including 2000 mg Myoinositol and 200 mcg Folic Acid Made by Teb Mofid Nikan Every 12 Hours with their Routine Medications for 8 Weeks Before the Start of the IVF Cycle and then Embryo Transfer will be Done with Appropriate Quality, Embryo and Oocyte quality and the Level of Laboratory Criteria (LH, FSH, FBS, Testosterone) and BMI will be Checked

Category

Treatment - Drugs

2

Description

Control group: Patients in the Control Group Received Inofolic Powder Including 2000 mg Myoinositol and 200 mcg Folic Acid Made by Teb Mofid Nikan Every 12 Hours with their Routine Medications for 8 Weeks Before the Start of the IVF Cycle and then Embryo Transfer will be Done with Appropriate Quality, Embryo and Oocyte quality and the Level of Laboratory Criteria (LH, FSH, FBS, Testosterone) and BMI will be Checked

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashan Shahid Beheshti Hospital

Full name of responsible person

Mahdis Rajabi

Street address

Ghotbe Ravandi Blv, Shahid Beheshti Hospital

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8715988111

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Email

beheshtihospital@kaums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Doctor Gholamali Hamidi

Street address

Tahghighat & Fanavari Moavenat , Kashan Medical Science University

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8715981151

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hamiidi@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kashan 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

Kashan University of Medical Sciences

Full name of responsible person

Fateme Foroozanfard

Position

Associate Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Mahdis Rajabi

Position

resident

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for updating data

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Mahdis Rajabi

Position

resident

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

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Email

Mahdiis174@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available