Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The effect of inositol on fertility in Frozen embryo transfer cycles in Poly cystic ovary syndrome

Protocol summary

Study aim
Determining the effect of inositol consumption on fertility in frozen embryo transfer cycles in people with polycystic ovary syndrome.

Design
Patients who meet the entry criteria will be randomly divided into two groups by block balanced randomization using the Random Allocation software.

Settings and conduct
The current research is a double-blind clinical trial study that will be conducted in Shahid Beheshti Hospital, Kashan.

Participants/Inclusion and exclusion criteria
Inclusion criteria: People with polycystic ovary syndrome who are between 20 and 40 years old and based on sonographic and laboratory findings included in the PCOS case file and based on infertility records are candidates for FET procedure at Shahid Beheshti Hospital Infertility Center. They are Kashan.

Intervention groups
According to coordination with the pharmacy of Shahid Beheshti Hospital in Kashan, the considered drugs are provided to the patients in two packages A and B. Patients in the control group will receive package A, which includes their routine medications, plus folic acid, which is produced with a similar appearance by a reputable pharmaceutical company, and patients in the intervention group will receive package B, which includes their routine medications plus inofolic. Patients in the control group will take folic acid for 8 weeks before the date of embryo transfer, and the intervention group will receive inofolic powder along with their routine medications for eight weeks.

Main outcome variables
Pregnancy rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220809055652N1**
Registration date: **2023-09-22, 1402/06/31**
Registration timing: **retrospective**

Last update: **2023-09-22, 1402/06/31**
Update count: **0**

Registration date
2023-09-22, 1402/06/31

Registrant information

Name
Zohreh Talebi Mazreshahi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 31 5558 9258

Email address
talebi-z@kaums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-10-02, 1401/07/10

Expected recruitment end date
2022-11-01, 1401/08/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of inositol on fertility in Frozen embryo transfer cycles in Poly cystic ovary syndrome

Public title
The effect of inositol on fertility in Frozen embryo transfer cycles in Poly cystic ovary syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
People with polycystic ovary syndrome based on sonographic and laboratory findings. Ages between 20 and 40 years old Candidate to enter the FET procedure at Infertility Center of Shahid Beheshti Hospital, Kashan, based on infertility records.
Exclusion criteria:
People with uterine abnormalities (such as Asherman's syndrome, fibroids, polyps and adenomyosis diagnosis) Inositol contraindications Treatment cycles with embryo donation or prenatal genetic screening, The mother is over 40 years old Endometriosis Unexplained Infertility
Age
From **20 years** old to **40 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
It will be done by simple random method and using lottery. Each patient will receive a number or code. We will write the numbers on pieces of paper. Then we will put the pieces of paper in a container and select the samples for the intervention and control groups according to the sample size from the numbers obtained from the lottery.
Blinding (investigator's opinion)
Double blinded
Blinding description
According to coordination with the pharmacy of Shahid Beheshti Hospital in Kashan, the considered drugs are provided to the patients in two packages A and B. Patients in the control group will receive package A, which includes their routine medications, plus folic acid, which is produced with a similar appearance by a reputable pharmaceutical company, and patients in the intervention group will receive package B, which includes their routine medications plus inofolic.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee in Research of Faculty of Medicine, Kashan University of Medical Sciences
Street address
Faculty of Medicine, Kashan University of Medical Sciences, Qotb-e Ravandi Blvd, Kashan, Isfahan province, Iran. Post code:8715988111
City
Kashan
Province
Isfehan
Postal code
8715988111
Approval date
2022-07-26, 1401/05/04
Ethics committee reference number
IR.KAUMS.MEDNT.REC.1401.072

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
Fertility rate
Timepoint
Two months
Method of measurement
Clinical examination of pregnancy with the criterion of fetal heart observation in ultrasound

Secondary outcomes

empty

Intervention groups

1

Description
Control group: Control group: According to coordination with the pharmacy of Shahid Beheshti Hospital in Kashan, the drugs considered in this study are provided to the patients in two packages A and B. Patients in the control group received Package A, which included their own routine medications plus folic acid manufactured in a similar form by a reputable pharmaceutical company.

These patients take folic acid for 8 weeks before the embryo transfer date, and then the embryo transfer is done with a suitable quality and the biochemical pregnancy rate (slight and temporary increase in B-hCG level), Clinical Pregnancy rate (observation of the fetus with activity heart in 6-7 weeks of pregnancy) and the rate of spontaneous abortion (pregnancy loss in 5-12 weeks of pregnancy) will be investigated in this group.

Category

Treatment - Drugs

2

Description

Intervention group: According to coordination with Shahid Beheshti Kashan hospital pharmacy, the drugs considered in this study are provided to the patients in two packages A and B. Patients in the intervention group will receive package B, which includes their routine medications along with inofolic. The patients of the intervention group received these drugs for eight weeks and then the embryo transfer was done with good quality and the amount of biochemical pregnancy (slight and temporary increase in B-hCG level), the amount of clinical pregnancy (observation of the fetus with cardiac activity in 6 weeks) 7-pregnancy) and the rate of spontaneous abortion (pregnancy loss in 5-12 weeks of pregnancy) will be investigated in this group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital, Kashan

Full name of responsible person

Zohreh Talebi Mazreshahi

Street address

Shahid Beheshti Hospital, Qotb-e Ravandi Blvd, Kashan, Isfahan province, Iran. Post code:8715988111

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Talebi-z@kaums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Gholam Ali Hamidi

Street address

Faculty of Medicine, Kashan University of Medical Sciences, Qotb-e Ravandi Blvd, Kashan, Isfahan province, Iran. Post code:8715988111

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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

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

Zohreh Talebi Mazreshahi

Position

Gynecology and obstetrics surgeon

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Kashan University of Medical Sciences

Full name of responsible person
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Position
Gynecology and obstetrics surgeon

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Person responsible for updating data

Contact

Name of organization / entity
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Full name of responsible person
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Position
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Latest degree
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Other areas of specialty/work
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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
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available