# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

13 Jun 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)

**Phone**
+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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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Kashan University of Medical Sciences

**Full name of responsible person**

Gholam Ali Hamidi

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

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research@kaums.ac.ir

**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

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## Person responsible for scientific inquiries

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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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## 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