

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Study the effects of pretreatment with myoinositol on oocyte quality in PCOS patients undergoing multiple follicular stimulation for IVF/ICSI

Protocol summary

Summary

The aim of this study is to determine the effects of pretreatment with myoinositol on oocyte quality in PCOS patients undergoing multiple follicular stimulation for IVF/ICSI. Results of this study will suggest an appropriate method which can be used for PCOS patients candidates for IVf with the least side effects and in shortest possible time. The study population are infertile women with PCOS candidates for IVF. 54 patients participate in this study which divided to 2 groups in a randomized controlled double blind trial. In one group the patients will take only folic acid 400 mg /day for 3 months and in the second group patients will take folic acid 400 mg/day +myoinositol 2000 mg for 3 months. After that both groups will enter to ovulation induction cycles by antagonist protocol. The result of cycles will be measured as OHSS event, oocytes quantity and quality, ovums and clinical pregnancy. One of the important inclusion criterias is normal sperm test and hysterosalpingography and the patients must not use any other medication during the study and do not have any underlying disease. The most important primary outcome measure is clinical pregnancy as outcome of cycles and OHSS event will be considered as the secondary outcome measure.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017021432525N2**

Registration date: **2017-04-30, 1396/02/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-04-30, 1396/02/10

Registrant information

Name

Shadrooz Moazzam

Name of organization / entity

Shahrekord University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Shahrekord University of Medical Sciences

Expected recruitment start date

2016-04-20, 1395/02/01

Expected recruitment end date

2016-07-22, 1395/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study the effects of pretreatment with myoinositol on oocyte quality in PCOS patients undergoing multiple follicular stimulation for IVF/ICSI

Public title

Study the effects of pretreatment with myoinositol on oocyte quality in patients with polycystic ovary syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

inclusion criteria: infertile women with PCOS over 35 years old candidate for IVF procedure; normal sperm test

and hysterosalpingography;agreement of patients for participation in the study. exclusion criteria:patients must not use any other medication during the study;any other disease,history of abdomen and pelvic surgery,male infertility,abnormal hysterosalpingography or abnormal prolactin level;patients leave the study on their own decision

Age

From **35 years** old to **60 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **54**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

ethics committee of Shahrekord University of Medical Sciences

Street address

Kashani street, Shahrekord

City

Shahrekord

Postal code

Approval date

2016-10-01, 1395/07/10

Ethics committee reference number

IR.SKUMS.REC.1395.116

Health conditions studied

1

Description of health condition studied

polycystic ovary syndrome disorder

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovarian syndrome

Primary outcomes

1

Description

cancelled cycles

Timepoint

3 months after intervention

Method of measurement

observation

2

Description

cycles which lead to freeze

Timepoint

3 months after intervention

Method of measurement

observation

3

Description

chemical and clinical pregnancy

Timepoint

3 months after intervention

Method of measurement

pregnancy proved by positive beta HCG test ,14 days after ovum transportation and sonography approved

4

Description

ovum grade

Timepoint

3 months after intervention

Method of measurement

A -D observation

5

Description

PVS quality

Timepoint

3 months after intervention

Method of measurement

observation

6

Description

fertilized egg

Timepoint

3 months after intervention

Method of measurement

observation

7

Description

zona pellucida quality

Timepoint

3 months after intervention

Method of measurement

observation

8**Description**

cleavage rate

Timepoint

3 months after intervention

Method of measurement

observation

9**Description**

metaphase II oocytes quality

Timepoint

3 months after intervention

Method of measurement

observation

10**Description**

number of metaphase II oocytes

Timepoint

3 months after intervention

Method of measurement

observation

11**Description**

number of atretic and immature oocytes (GV and metaphase II phases and degenerated oocytes)

Timepoint

3 months after intervention

Method of measurement

observation

Secondary outcomes**1****Description**

hospitalization rate because of OHSS(ovary hyperstimulation syndrome)

Timepoint

3 months after intervention till end of pregnancy

Method of measurement

number of hospitalizations of patients due to this reason ,observation

Intervention groups**1****Description**

myoinositol 2000 mg +400 mg folic acid daily for 3 months

Category

Treatment - Drugs

2**Description**

400 mg folic acid daily for 3 months

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Alzahra Infertility Clinic

Full name of responsible person

Shadrooz Moazzam

Street address

Saman Gate, Shahrekord

City

Shahrekord

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shahrekord University of Medical Sciences

Full name of responsible person

Dr Solati

Street address

Kashani street, Shahrekord

City

Shahrekord

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shahrekord University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Shahrekord University of Medical Sciences

Full name of responsible person

Shadrooz Moazzam

Position

medical intern

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Full name of responsible person

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Position

obstetrics and gynecologist

Other areas of specialty/work**Street address**

Alzahra infertility clinic

City**Postal code****Phone**

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Fax**Email****Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty