

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of effectiveness of inositol and metformin in infertile women with polycystic ovary syndrome (PCOS) treated with letrozole and gonadotropin

Protocol summary

Summary

Aim of study: Comparison of effectiveness of inositol and metformin in infertile women with polycystic ovary syndrome (PCOS) treated with letrozole and gonadotropin. Study design: one blind randomized. Study population: this study is a randomized single blind controlled clinical trial undertaken in 80 infertile PCOS women from 2015-2016. Inclusion criteria: Patients with polycystic ovary syndrome according to Rotterdam criteria; age 15-38 years old. Exclusion criteria: no desire to cooperation. Study sample: 80 people. Intervention: For all patients, letrozole is prescribed at a dose of 2.5 mg per day from the third day of menstruation for 5 days. The patients were then evaluated during 12 to 16 menstrual cycles to evaluate the response to the drug, the size of the follicles reached in the ovary and the thickness of the endometrium by vaginal ultrasonography. When at least one mature follicle is seen, injections of 10,000 units of gonadotrophin are injected. Patients who did not ovulate after letrozole for a continuous dose of 7.5 mg after three continuous cycles were included in the study and were divided into three groups: in group 1, inositol 2 g plus 200 micrograms of folic acid twice daily; group II, 1500 mg of metformin daily plus 200 micrograms of folic acid and group 3, 200 micrograms of folic acid (as a placebo) for three months. Primary outcomes: ovary function, pregnancy.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017070234845N1**

Registration date: **2017-10-02, 1396/07/10**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-10-02, 1396/07/10

Registrant information

Name

Sajadeh Pourghasem

Name of organization / entity

Hormozgan University of Medical Science

Country

Iran (Islamic Republic of)

Phone

Email address

pourghasem@hums.ac.ir

Recruitment status

Recruitment complete

Funding source

Hormozgan University of Medical Sciences

Expected recruitment start date

2016-03-19, 1394/12/29

Expected recruitment end date

2017-03-20, 1395/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of effectiveness of inositol and metformin in infertile women with polycystic ovary syndrome (PCOS) treated with letrozole and gonadotropin

Public title

Comparison of effectiveness of inositol and metformin in infertile women with polycystic ovary syndrome (PCOS)

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Patients with polycystic ovary syndrome according to Rotterdam criteria; age 15-38 years old. Exclusion criteria: no desire to cooperation

Age
From **15 years** old to **38 years** old

Gender
Female

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Hormozgan University of Medical Sciences

Street address
No. 7916839319, Vice chancellor for research, Shahid Mohammadi hospital, Bandarabbas Bandarabbas

City
Bandarabbas

Postal code

Approval date
2016-09-22, 1395/07/01

Ethics committee reference number
HUMS.REC.1395.019

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
Ovary function

Timepoint
monthly

Method of measurement
Follicole size more than 16 mm

Secondary outcomes

1

Description
pregnancy

Timepoint
monthly

Method of measurement
pregnancy test

Intervention groups

1

Description
group 1, inositol 2 g plus 200 micrograms of folic acid twice daily; group II , 1500 mg of metformin daily plus 200 micrograms of folic acid and group 3, 200 micrograms of folic acid (as a placebo) for three months

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Gynecological clinic of Khaliye-fars Hospital

Full name of responsible person

Street address

City
Bandarabbas

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Hormozgan University of Medical Science

Full name of responsible person
Dr Teymor Aghamolaei

Street address
No. 7916839319, Vice chancellor for research, Shahid Mohammadi hospital, Bandarabbas Bandarabbas

City
Bandarabbas

Grant name

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

Yes

Title of funding source

Hormozgan University of Medical Science

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

Hormozgan University of Medical Science

Full name of responsible person

Dr Sajadeh Pourghasem

Position

Ph.D. in Obstetrics and Gynecology

Other areas of specialty/work

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No. 7916839319, Vice chancellor for research, Shahid

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Person responsible for scientific inquiries

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Full name of responsible person

Dr Sajadeh Pourghasem

Position

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Other areas of specialty/work

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Person responsible for updating data

Contact

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Full name of responsible person

Position

Other areas of specialty/work

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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