

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

The effects of MYO- Inositol and metformin on oxidative stress and homocysteine levels in patients with polycystic ovary syndrome

Protocol summary

Study aim

Evaluation of the effect of metformin and inofollic on the level of homocysteine and oxidative stress in patients with polycystic ovary syndrome.

Design

Clinical trial, parallel, double-blind, randomized trials

Settings and conduct

In this study, patients with polycystic ovary syndrome are randomly divided into two groups: metformin and inofollic. After three months receiving the medication, the amount of homocysteine and their oxidative stress factors are compared. The patient and the investigator are not aware of the type of drug used.

Participants/Inclusion and exclusion criteria

The inclusion criteria PCO patients The exclusion criteria diabetes mellitus, hyperprolactinemia, congenital adrenal hyperplasia, thyroid disorders, Cushing's syndrome, hypertension, folate and vitamin B12 deficiency, liver and kidney disorders.

Intervention groups

First group of metformin, second group of inofollic

Main outcome variables

Homocysteine, Folic Acid, Vitamin B12, Malondialdehyde, Plasma total antioxidant

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190508043516N1**

Registration date: **2019-07-28, 1398/05/06**

Registration timing: **registered_while_recruiting**

Last update: **2019-07-28, 1398/05/06**

Update count: **0**

Registration date

2019-07-28, 1398/05/06

Registrant information

Name

Nasim Athari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3446 2568

Email address

atharinasim@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-23, 1397/07/01

Expected recruitment end date

2019-09-23, 1398/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of MYO- Inositol and metformin on oxidative stress and homocysteine levels in patients with polycystic ovary syndrome

Public title

The effects of MYO- Inositol and metformin on oxidative stress and homocysteine levels in patients with polycystic ovary syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Polycystic ovary syndrome

Exclusion criteria:

Diabetes mellitus Hyperprolactinemia Congenital adrenal

hyperplasia Thyroid disorders Cushing's syndrome Liver and kidney disorders Hypertension Hemoglobinopathy

IR.DUMS.REC.1397.037

Age

From **15 years** old to **35 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly divided into two distinct and equal groups according to random randomization. In this way, they are divided into two groups A (metformin) and B (inofollic), and 6 blocks of 1-AABB 2-ABAB 3- ABBA 4-BBAA-5ABAB 6- BABA are considered for them, respectively, according to the incidence of patients And according to the blocks (1 to 6) received the medication.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patient does not see the label of the drug. The researcher does not know the type of drug patient receives. The data analyzer does not know the patient's medication.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Dezful University of Medical Sciences

Street address

Dezful University of Medical Sciences, Azadegan Blvd

City

Dezful

Province

Khouzestan

Postal code

6461665145

Approval date

2018-07-27, 1397/05/05

Ethics committee reference number

Health conditions studied

1

Description of health condition studied

Polycystic ovary syndrome

ICD-10 code

E28.2

ICD-10 code description

Polycystic ovary syndrome

Primary outcomes

1

Description

Homocysteine

Timepoint

Beginning of study, three months after the intervention

Method of measurement

Elisa kit

2

Description

Oxidative stress factors

Timepoint

Beginning of study, three months after the intervention

Method of measurement

Elisa kit

Secondary outcomes

empty

Intervention groups

1

Description

intervention group1: metformin twice a day at 850 mg for 3 months

Category

Treatment - Drugs

2

Description

Intervention group2: 4 g of Myoinositol daily with 400 µg of folic acid (inofollic) for 3 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dezful university of medical science

Full name of responsible person

Nasim Athari

Street address

Dezful university of medical science, Azadegan Blvd

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Postal code

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Position

Medical intern

Latest degree

A Level or less

Other areas of specialty/work

Gynecology and Obstetrics

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

Dezful University of Medical Sciences

Full name of responsible person

Aziz Kasani

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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

Dezful 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**

Dezful University of Medical Sciences

Full name of responsible person

Nasim athari

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

Dezful University of Medical Sciences

Full name of responsible person

Nasim athari

Position

Medical intern

Latest degree

A Level or less

Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Dezful University of Medical Sciences

Full name of responsible person

Nasim athari

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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

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