

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

Clinical trial of the effect of inofolic supplementation compared with metformin on parameters of mental health and oxidative stress in women with polycystic ovary syndrome

Protocol summary

Study aim

The aim of this study is to determine the effects of inofolic supplementation compared with metformin on parameters of mental health and oxidative stress in patients of polycystic ovary syndrome (PCOS).

Design

Study design: Parallel clinical trial. Randomization will be done by the use of computer-generated random numbers.

Settings and conduct

Population and sample size: Among patients with PCOS referred to Kosar Clinic affiliated to Arak University of Medical Sciences, 60 patients will be selected according to inclusion and exclusion criteria.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with PCOS according to Rotterdam criteria will be included in this study.
Exclusion criteria: The intake of folate supplements within the last 3 months, pregnant women, individuals with metabolic diseases, thyroid disease, hyperprolactinemia and hypercortisolemia.

Intervention groups

Intervention: Patients will be assigned into two groups to receive inofolic (n=30) or metformin (n=30).

Main outcome variables

Outcomes: Parameters of mental health (primary outcomes) and oxidative stress (secondary outcome) will be quantified at study baseline and end-of-trial.

General information

Reason for update

The updating process was done after publishing the paper to correct the registration information.

Acronym

IRCT registration information

IRCT registration number: **IRCT201706065623N118**

Registration date: **2017-07-04, 1396/04/13**

Registration timing: **retrospective**

Last update: **2023-04-05, 1402/01/16**

Update count: **2**

Registration date

2017-07-04, 1396/04/13

Registrant information

Name

Zatollah Asemi

Name of organization / entity

Kashan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2016-06-14, 1395/03/25

Expected recruitment end date

2016-07-17, 1395/04/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of the effect of inofolic supplementation compared with metformin on parameters of mental

health and oxidative stress in women with polycystic ovary syndrome

Public title

Effect of supplementation in treatment of women with polycystic ovary syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with PCOS according to Rotterdam criteria

Exclusion criteria:

Smokers The intake of folate supplements within the last 3 months Pregnant women Individuals with metabolic diseases Thyroid disease Hyperprolactinemia and hypercortisolemia

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

At study baseline and after balanced blocked randomization, subjects will be randomly divided into two groups to take either inofolic supplementation or metformin. Randomization will be done by the use of computer-generated random numbers.

Blinding (investigator's opinion)

Not 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 Arak University of Medical Sciences

Street address

Vice chancellor for research, Arak University of Medical Sciences, Sardasht Avenue, Arak

City

Arak

Province

Markazi

Postal code

3819693345

Approval date

2016-06-13, 1395/03/24

Ethics committee reference number

IR.ARAKMU.REC.1395.110

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

Beck scor

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Questionnaire

2

Description

GHQ score

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Questionnaire

3

Description

DASS-28 score

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Total antioxidant capacity

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

2

Description

Total glutathione

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

3

Description

Malondialdehyde

Timepoint

At the beginning of the study and after 12 weeks of intervention

Method of measurement

Spectrophotometry

Intervention groups

1

Description

Intervention group: Inofolic supplements (Loli, Rome, Italy), 2000 mg myo-inositol, 200 µg folic acid, twice a day, for 12 weeks orally.

Category

Treatment - Drugs

2

Description

Control group: Metformin tablet (Tehran Darou, Tehran, Iran), according to the patient's tolerance, daily for 12 weeks orally.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kosar Clinic

Full name of responsible person

Mehri Jamilian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Arak University of Medical Sciences

Full name of responsible person

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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

Vice chancellor for research, Arak 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

Zatollah Asemi

Position

PhD of Nutrition

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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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