Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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

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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
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Other areas of specialty/work
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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