

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

Clinical trial of the effect of inofolic supplementation compared with metformin on metabolic profiles 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 metabolic profiles in women with 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 and aged 18–40 years old will be included in this study. Exclusion criteria: Women who were pregnant during the intervention, adrenal hyperplasia, androgen-secreting tumors, hyperprolactinemia, thyroid dysfunction, diabetes or impaired glucose tolerance

Intervention groups

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

Main outcome variables

Outcomes: Total testosterone (primary outcomes), inflammatory factors, and gene expression related to inflammation (secondary outcome) will be quantified at study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT201701295623N105**

Registration date: **2017-02-09, 1395/11/21**

Registration timing: **retrospective**

Last update: **2019-09-25, 1398/07/03**

Update count: **1**

Registration date

2017-02-09, 1395/11/21

Registrant information

Name

Zatollah Asemi

Name of organization / entity

Kashan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 36 1534 3570

Email address

asemi_z@kaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Arak University of Medical Sciences

Expected recruitment start date

2016-11-15, 1395/08/25

Expected recruitment end date

2016-11-30, 1395/09/10

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 metabolic profiles 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. Aged 18 to 40 years.

Exclusion criteria:

Women who were pregnant during the intervention
Adrenal hyperplasia Androgen-secreting tumors
Hyperprolactinemia Thyroid dysfunction Diabetes or impaired glucose tolerance

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

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

Isfahan

Postal code

3819693345

Approval date

2016-11-14, 1395/08/24

Ethics committee reference number

IR.ARAKMU.REC.1395.309

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

Total testosterone

Timepoint

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

Method of measurement

Elisa kit

Secondary outcomes

1

Description

Hs-CRP

Timepoint

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

Method of measurement

Elisa kit

2

Description

Nitric oxide

Timepoint

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

Method of measurement

Spectrophotometry

3

Description

Expressed levels of LL-1 gene

Timepoint

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

Method of measurement

PCR

4

Description

Expressed levels of IL-8 gene

Timepoint

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

Method of measurement

PCR

5

Description

Expressed levels of TNF-a gene

Timepoint

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

Method of measurement

PCR

6

Description

SHBG

Timepoint

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

Method of measurement

Elisa kit

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, 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

Street address

Emam Khomeyni Avenue, Arak

City

Arak

Province

Isfahan

Postal code

3819691187

Phone

+98 38 1969 3345

Email

mjamilian@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Vice chancellor for research, Arak University of Medical Sciences

Full name of responsible person

Mohammad Rafiee

Street address

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

City

Arak

Province

Markazi

Postal code

3819693345

Phone

+98 86 3313 6055

Email

info@arakmu.ac.ir

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

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

1771844351

Phone

+98 31 5546 3378

Email

asemi_z@kaums.ac.ir

Person responsible for scientific 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

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

8115187159

Phone

+98 31 5546 3378

Fax**Email**

asemi_z@kaums.ac.ir

Web page address**Person responsible for updating data****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

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfahan

Postal code

8115187159

Phone

+98 31 5546 3378

Fax**Email**

asemi_z@kaums.ac.ir

Web page address**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