

# 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 and gene expression related to insulin and lipid in women with polycystic ovary syndrome

#### Protocol summary

##### Study aim

Objective: The aim of this study is to determine the effects of inofolic supplementation on metabolic profiles and gene expression related to insulin and lipid in patients with polycystic ovary syndrome (PCOS).

##### Design

Study design: Randomized controlled trial.  
Randomization will be done by the use of computer-generated random numbers. Patients will be assigned into two groups to receive supplements (n=30) or control (n=30).

##### Settings and conduct

Among patients with gestational diabetes referred to Kosar outpatient Clinic affiliated to Arak University of Medical Sciences, 60 patients will be selected according to inclusion and exclusion criteria. Fasting blood samples will be taken at baseline and 12 weeks after the intervention. At the beginning and the end of the intervention: 12 weeks.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with polycystic ovary syndrome aged 18 to 40 years. Exclusion criteria: Pregnancy, adrenal hyperplasia, androgen-secreting tumors, hyperprolactinemia, thyroid dysfunction, diabetes.

##### Intervention groups

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

##### Main outcome variables

Outcomes: Glycemic control (primary outcomes), lipid profiles, and gene expression related to insulin and lipid (secondary outcome) will be quantified at study baseline and end-of-trial.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017082733941N10**

Registration date: **2017-09-18, 1396/06/27**

Registration timing: **retrospective**

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

Update count: **1**

##### Registration date

2017-09-18, 1396/06/27

##### Registrant information

###### Name

Mohammadreza Sharif

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 5546 3378

###### Email address

ostadmohammadi-vr@kaums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research, Arak University of Medical Sciences

##### Expected recruitment start date

2017-08-15, 1396/05/24

##### Expected recruitment end date

2017-08-30, 1396/06/08

##### 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 and gene expression related to insulin and lipid in women with polycystic ovary syndrome

## Public title

Effect of inofolic 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:

Pregnancy Adrenal hyperplasia Androgen-secreting tumors Hyperprolactinemia Thyroid dysfunction Diabetes

## Age

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

## Gender

Female

## Phase

N/A

## Groups that have been masked

- Outcome assessor

## Sample size

Target sample size: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

To decrease potential confounding effects, all participants will have stratified randomization according to BMI (<25 and  $\geq$ 25 kg/m<sup>2</sup>) and age (<30 and  $\geq$ 30 y). Then, participants in each block will be randomly allocated into two treatment groups to take either supplements or control. Randomization will be done by the use of computer software.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

The assessors of the outcomes are unaware of the study groups.

## 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

## City

Arak

## Province

Markazi

## Postal code

3848176941

## Approval date

2017-08-14, 1396/05/23

## Ethics committee reference number

IR.ARAKMU.REC.1396.90

## Health conditions studied

### 1

#### Description of health condition studied

Polycystic ovary syndrome

#### ICD-10 code

E28.2

#### ICD-10 code description

Polycystic ovarian syndrome

## Primary outcomes

### 1

#### Description

Insulin

#### Timepoint

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

#### Method of measurement

Elisa kit

### 2

#### Description

Insulin resistance

#### Timepoint

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

#### Method of measurement

Calculation using HOMA formula

## Secondary outcomes

### 1

#### Description

Total cholesterol

#### Timepoint

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

#### Method of measurement

Enzymatic kit

### 2

#### Description

HDL

### **Timepoint**

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

### **Method of measurement**

Enzymatic kit

## **3**

### **Description**

Triglycerides

### **Timepoint**

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

### **Method of measurement**

Enzymatic kit

## **4**

### **Description**

Expressed levels of PPAR-γ gene

### **Timepoint**

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

### **Method of measurement**

PCR

## **5**

### **Description**

Expressed levels of GLUT-1 gene

### **Timepoint**

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

### **Method of measurement**

PCR

## **6**

### **Description**

VLDL

### **Timepoint**

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

### **Method of measurement**

Enzymatic kit

## **7**

### **Description**

Expressed levels of LDLR gene

### **Timepoint**

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

### **Method of measurement**

PCR

## **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**

Maryam Shokrpour

##### **Street address**

Emam Khomeyni Avenue, Arak

##### **City**

Arak

##### **Province**

Markazi

##### **Postal code**

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##### **Phone**

+98 86 3417 3645

##### **Email**

Shokrpour-m@aums.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**

Ali Arash Anoushirvani

##### **Street address**

Vice chancellor for research, Arak University of Medical Sciences

##### **City**

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##### **Postal code**

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##### **Phone**

+98 86 3417 3645

##### **Email**

Anoushirvani-aa@aums.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**

Ph.D of Nutrition

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

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

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**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

**Street address**

Ghotbe Ravandi Boulevard, Kashan

**City****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