

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### Evaluating the effect of consumption of synbiotic pomegranate juice on glycemic markers, oxidative stress, inflammation and androgen profile of women with poly cystic ovarian syndrome

#### Protocol summary

2017-10-17, 1396/07/25

##### Summary

Polycystic ovary syndrome (PCOS) is one of the most common gynecological diseases that is associated with endocrine and metabolic disorders. The causes of the pathogenesis of PCOS are insulin resistance, oxidative stress and imbalance of intestinal microflora. The disturbances observed in these patients include increased blood androgen, menstrual irregularities, polycystic ovarian ultrasound findings, increased hair, acne, Hypransulinemia, glucose intolerance, dyslipidemia and abdominal obesity. Now a day Due to the side effects of synthetic drugs on the body, is still the subject of much research on the health effects of different foods. Since the pomegranate juice and synbiotic may improve oxidative stress levels, inflammation, reduce insulin resistance and improve the balance of gut microflora and other abnormalities were observed in subjects such as dyslipidemia and cardiovascular complications, and in addition phytoestrogens found in pomegranate may be able to improve these people to be involved in disorders of sex hormones, so The present study aimed to investigate the effect of pomegranate juice a synbiotic on the glycemic index, oxidative stress, inflammatory markers, androgen profile, lipid profile in women with polycystic ovary syndrome is designed.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017020732439N1**

Registration date: **2017-10-17, 1396/07/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

##### Registrant information

###### Name

Zahra Esmaeilinezhad

###### Name of organization / entity

food and nutrition science university

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 3225 7162

###### Email address

stud2560185261@sums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

nutritional university

##### Expected recruitment start date

2017-01-20, 1395/11/01

##### Expected recruitment end date

2017-08-22, 1396/05/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluating the effect of consumption of synbiotic pomegranate juice on glycemic markers, oxidative stress, inflammation and androgen profile of women with poly cystic ovarian syndrome

##### Public title

Evaluating the effect of consumption of synbiotic pomegranate juice in women with poly cystic ovarian syndrome

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion criteria PCOS could be diagnosed, according to the ROTTERDAM criteria, by two of the following three features: 1) Oligomenorrhea (Less Than 6-9 Menses per Year) or amenoria (Non-vaginal bleeding for at least 6 months) 2) Clinical Hyperandrogenism (Hirsutism score higher than 8 or obviose acne) or increase blood testosterone levels (Testosterone levels above2 nmo/l) 3) Polycystic Ovaries on Ultrasound (The presence of 12 or more cysts with a diameter of 9.2 mm in one or both ovaries or the size of the ovary 10 cm<sup>3</sup> or more) BMI>18 Having permission the doctor and informed consent to participate in the study Not Inclusion criteria: Other medical conditions related to excess androgens such as increased blood prolactin, nonclassical congenital adrenal hyperplasia, Cushing's syndrome, androgen-producing tumors and acromegaly wemon with severe diseases of the stomach, intestines, heart, kidney, liver, lung, chronic, autoimmune, inflammatory and AIDS Patients undergoing chemotherapy smokers Lactating women Patients treated with corticosteroids and antibiotics The use of supplements of vitamins, minerals and antioxidants Those taking hormone pills or supplements Patients using insulin to treat diabetes Patients with a special diet Patients with specific exercise program Exclusion criteria: Lack of any of the compounds at a rate of more than 4 days a week The loss of any of the inclusion criteria

## Age

From **15 years** old to **48 years** old

## Gender

Female

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **92**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Triple blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

We randomly assigned patients to a ratio of 1: 1: 1: 1 to 4 groups. A scholar who did not have any clinical intervention in intervention, randomly classified the patient by random blocking software with a fixed block size of 4 in randomized group In order to blind patients, the drinks in all groups are identical in appearance, color and taste. The drinks are coded deffrently in each group and then will be given to scholar to blinding the scholar. Finally, the data and information are also given to the analyzer by the special code for each group in order to be blinded analyzer.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciences

##### Street address

razi street

##### City

shiraz

##### Postal code

#### Approval date

2017-01-22, 1395/11/03

#### Ethics committee reference number

IR.SUMS.REC.1395.168

## Health conditions studied

### 1

#### Description of health condition studied

poly cystic ovarian syndrome

#### ICD-10 code

E28.2

#### ICD-10 code description

Polycystic ovarian syndrome

## Primary outcomes

### 1

#### Description

fasting blood glucose

#### Timepoint

before and 2 month after intervention

#### Method of measurement

enzymatic colorimetric method

### 2

#### Description

fasting plasma insulin

#### Timepoint

before and 2 month after intervention

#### Method of measurement

Enzyme-linked immunosorbent assay ( ELISA )

### 3

#### Description

insulin resistente

#### Timepoint

before and 2 month after intervention

#### Method of measurement

HOMA-IR

## 4

### **Description**

insulin sensitivity

### **Timepoint**

before and 2 month after intervention

### **Method of measurement**

QUICKI

## 5

### **Description**

hs-CRP

### **Timepoint**

before and 2 month after intervention

### **Method of measurement**

Enzyme-linked immunosorbent assay ( ELISA )

## 6

### **Description**

MDA

### **Timepoint**

before and 2 month after intervention

### **Method of measurement**

biochemichal method

## 7

### **Description**

TAC

### **Timepoint**

before and 2 month after intervention

### **Method of measurement**

calorimetric

## 8

### **Description**

DHEAS

### **Timepoint**

before and 2 month after intervention

### **Method of measurement**

Enzyme-linked immunosorbent assay ( ELISA )

## 9

### **Description**

testosterone

### **Timepoint**

before and 2 month after intervention

### **Method of measurement**

Enzyme-linked immunosorbent assay ( ELISA )

## **Secondary outcomes**

### 1

#### **Description**

mensturation cycle

#### **Timepoint**

before and 2 month after intervention

#### **Method of measurement**

questionare

### 2

#### **Description**

hirsutism

#### **Timepoint**

before and 2 month after intervention

#### **Method of measurement**

questionare

### 3

#### **Description**

alopecia

#### **Timepoint**

before and 2 month after intervention

#### **Method of measurement**

questionare

## **Intervention groups**

### 1

#### **Description**

1. Patients who receive 2 liters of pomegranate juice each week, which consists of pomegranate juice, enriched with inulin and lactobacillus, in the form of disposable bottles for 8 weeks.

#### **Category**

Treatment - Other

### 2

#### **Description**

2. Patients who receive 2 liters of pomegranate juice each week, in the form of disposable bottles for 8 weeks.

#### **Category**

Treatment - Other

### 3

#### **Description**

3. Patients who receive 2 liters of synbiotic juice each week, which consists of inulin, lactobacillus and pomegranate flavor, in the form of disposable bottles for 8 weeks.

#### **Category**

Treatment - Other

### 4

#### **Description**

4. Patients who receive 2 liters of placebo juice each week, which consists of pomegranate flavore, in the form of disposable bottles for 8 weeks.

#### **Category**

Placebo

## **Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Motahari Clinic

**Full name of responsible person**

Mrs. Dr. Amoei Gynecologist

**Street address**

Namazai Square

**City**

Shiraz

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Research Associate, Faculty of Nutrition and Food Sciences

**Full name of responsible person**

Dr Babajafari

**Street address**

Razi street

**City**

Shiraz

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Research Associate, Faculty of Nutrition and Food Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Food and nutrition science university

**Full name of responsible person**

Zahra Esmaeilinezhad

**Position**

master of science student

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**Web page address**

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*  
**Analytic Code**  
*empty*

**Data Dictionary**  
*empty*