

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Evaluating the effect of consumption of synbiotic pomegranate juice on lipid profile, anthropometric markers and quality of life in women with Poly Cystic Ovarian Syndrome

Protocol summary

Study aim

1. Determine the effect of synbiotic pomegranate juice on serum total cholesterol, triglyceride, LDL-cholesterol, HDL-cholesterol, anthropometric measures, quality of life and quality of sleep related health in patients with PCOS.
2. Determination of the effect of pomegranate juice on serum total cholesterol, triglyceride, LDL-cholesterol, HDL-cholesterol, anthropometric measurements, quality of life and quality of sleep related health in patients with PCOS
3. Determine the effect of synbiotic drink on serum total cholesterol, triglyceride, LDL-cholesterol, HDL-cholesterol, anthropometric measures, quality of life and quality of sleep related health in patients with PCOS.
4. Comparison of coalytic, pomegranate juice and synbiotic properties on total serum cholesterol, triglyceride, LDL-cholesterol, HDL-cholesterol, anthropometric measurements, quality of life and quality of sleep related health in patients with PCOS.
5. Determination of the sensory and physicochemical properties of produced synthetic pomegranate juice

Design

In this study, 92 patients with pcos who were referred to the clinics of Shiraz were selected. The participants were randomly divided into four groups: Synbiotic Pomegranate juice Consumers Group, Pomegranate juice Consumers Group, Synbiotic Drink Consumers Group and Placebo Consumers Group are assigned.

Settings and conduct

In this study, 92 patients with pcos who were referred to the clinics of Shiraz were selected. The participants were randomly divided into four groups: Synbiotic Pomegranate juice Consumers Group, Pomegranate juice Consumers Group, Synbiotic Drink Consumers Group and Placebo Consumers Group are assigned. Patients receive 250 cc of their interventions for 8 weeks. This is a double-blind study.

Participants/Inclusion and exclusion criteria

PCOS could be diagnosed, after the exclusion of related disorders, by two of the following three features: Oligomenorrhea (Less Than 6-9 Menses per Year) or amenorrhea (no vaginal bleeding for at least 6 months); Clinical findings: Increased blood androgen levels (hirsutism higher than 7 or acne), or increased blood testosterone levels (testosterone levels above 2 nmol / l); Polycystic ovaries in ultrasound (presence of 12 or more cysts with a diameter of 9.2 mm inside one or both ovaries or the size of the ovary 10 cm 3 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 woman 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

Intervention groups

Synbiotic Pomegranate juice Consumers Group, Pomegranate juice Consumers Group, Synbiotic Drink Consumers Group and Placebo Consumers Group

Main outcome variables

Improved serum total cholesterol, triglyceride, LDL-cholesterol, HDL-cholesterol, anthropometric measurements, quality of life, and quality of sleep related health in patients with PCOS

General information

Reason for update

Acronym

synbiotic pomegranate juice

IRCT registration information

IRCT registration number: **IRCT20170207032439N2**

Registration date: **2017-12-14, 1396/09/23**

Registration timing: **retrospective**

Last update: **2017-12-14, 1396/09/23**

Update count: **0**

Registration date

2017-12-14, 1396/09/23

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

Food and Nutrition Science University

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2017-07-21, 1396/04/30

Actual recruitment start date

2017-02-19, 1395/12/01

Actual recruitment end date

2017-07-21, 1396/04/30

Trial completion date

empty

Scientific title

Evaluating the effect of consumption of synbiotic pomegranate juice on lipid profile, anthropometric markers and quality of life in 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:

Inclusion criteria PCOS could be diagnosed, after the exclusion of related disorders, by two of the following three features: Oligomenorrhea (Less Than 6-9 Menses per Year) or amenorrhea (no vaginal bleeding for at least 6 months); Clinical findings: Increased blood androgen levels (hirsutism higher than 7 or acne), or increased blood testosterone levels (testosterone levels above 2 nmol / l); Polycystic ovaries in ultrasound (presence of 12 or more cysts with a diameter of 9.2 mm inside one or both ovaries or the size of the ovary 10 cm 3 or more);

BMI>18; Having permission the doctor and informed consent to participate in the study

Exclusion 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

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Data analyser

Sample size

Target sample size: **92**

Actual sample size reached: **92**

Randomization (investigator's opinion)

Randomized

Randomization description

Balanced Block Randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

Beverages in all groups are identical in terms of appearance, color and taste. Drinks with different codes in each group will be given to blindness to the researcher and Finally, the data and information are also given to the statistics specialist by the special code for each group to make a blindfold for the statistics specialist.

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, randomly classified the patients by random blocking software with a fixed block size of 4 in randomized groups. In order to blind patients, the drinks in all groups are identical in appearance, color and taste. The drinks are coded differently in each group and then will be given to the scholar to blinde him. Finally, the data and information are also given to the analyzer with the special code for each group in order to blinde 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

Province

Fars

Postal code

881565368

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

IR.SUMS.REC.1395.189

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

Total Cholesterol

Timepoint

Before and 2 month after intervention

Method of measurement

Autoanalyzer

2

Description

Triglyceride

Timepoint

Before and 2 month after intervention

Method of measurement

Autoanalyzer

3

Description

HDL-C

Timepoint

Before and 2 month after intervention

Method of measurement

Autoanalyzer

4

Description

LDL-C

Timepoint

Before and 2 month after intervention

Method of measurement

Autoanalyzer

5

Description

Health-related quality of life in polycystic ovary syndrome patients

Timepoint

Before and 2 month after intervention

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Menstruation cycle

Timepoint

Before and 2 month after intervention

Method of measurement

Questionnaire

Intervention groups

1

Description

Patients who receive 2 liters of synbiotic 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

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

Category

Treatment - Other

3

Description

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

Category

Treatment - Other

4

Description

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

Province

Fars

Postal code

8876115956

Phone

+98 71 3725 1001

Email

reza89barati@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Siyavash Babajafari

Street address

Razi street

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Postal code

8876115956

Phone

+98 71 3725 1001

Email

reza93barati@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Zahra Esmaeilinezhad

Position

Masret of science student

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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sahar.esn8@gmail.com

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Person responsible for scientific inquiries

Contact

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Position

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Latest degree

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

Shiraz University of Medical Sciences

Full name of responsible person

Zahra Esmaeilinezhad

Position

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Latest degree

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Fax**Email**

reza89barati@yahoo.com

Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Information about the consequences is shared

When the data will become available and for how long

Since 2019

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

To evaluate the statistical analysis

From where data/document is obtainable

Reza Barati reza93barati@gmail.com

What processes are involved for a request to access data/document

Maximum one week after receiving the application

Comments