Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Evaluating the effect of consumption of synbiotic pomegranate juice on lipid profile, anthropometric markesrs 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-cholestrole, HDL-cholestrole, 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-cholestrole, HDL-cholestrole, 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-cholestrole, HDL-cholestrole, anthropometric measures, quality of life and quality of sleep related health in patients with PCOS.
4.Comparison of cobytic, pomegranate juice and synbiotic properties on total serum cholesterol, triglyceride, LDL-cholestrole, HDL-cholestrole, 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-cholestrole, HDL-cholestrole, 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 nutrion 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 markesrs 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; kidne; 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 patinets 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 analayzer.

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 Cholestrol
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
Questionaire

Secondary outcomes

1

Description
Mensturation cycle
Timepoint
Before and 2 month after intervention
Method of measurement
Questionare

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
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Province
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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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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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Person responsible for updating data

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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