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

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

2017-10-17, 1396/07/25

Registrant information

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Zahra Esmaeilinezhad
Name of organization / entity
food and nutrion science university
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Recruitment status

Recruitment complete

Funding source

nutritional universitye

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 cm3 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 citeria: 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 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
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 resistante
Timepoint
before and 2 month after intervention
Method of measurement
HOMA-IR

4

Description
insulin sensivity
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 nutrion science university
Full name of responsible person
Zahra Esmaeilinezhad
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masret of science student
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Person responsible for updating data

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00
Fax
Email
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