Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The Effect Of Concentrated Pomegranate Juice On Depression score , Insulin Resistance(HOMA-IR) , oxidative And Antioxidant Markers (TAC , MDA) In Women With Polycystic Ovary Syndrome(PCOS)

Protocol summary

Study aim

The effect of concentrated pomegranate juice on depression score , insulin resistance , oxidative and antioxidant markers in women with polycystic ovary syndrome.

Design

clinical trial, Randomized, non-blind, having Control group

Settings and conduct

First, we select 44 patients with PCOS who referre to Shahid Beheshti Clinic in Isfahan and divide into two groups. Participants were asked to record their 3-day dietary intake (2 days per week and one day off) and to complete the DASS questionnaire and the intervention is implemented.Then, anthropometric measurements and blood pressure are performed and their fasting blood samples are taken and then the intervention is performed. Individuals are asked not to alter their dietary intake, calorie intake, eating habits, and exercise routine during the study period. After 8 weeks, all of the above steps will be repeated.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 18≤age≤40, BMI ≥ 25, being single, not having acute and chronic diseases such as: cardiovascular disease, diabetes, hypothyroidism, hypertension, dyslipidemia, depression, not following a specific diet and exercise program, non-use of drugs such as oral contraceptive pill, hormonal drugs, anti-diabetic drugs, antioxidant supplements, not consuming pomegranates at least 2 months before the study. Exclusion criteria: pregnancy,not consuming concentrated pomegranate juice completely, not willing to continue participating in the study.

Intervention groups

we will give concentrated pomegranate juice 45 cc daily to the intervention group and and we say to dilute it with 180 cc water daily and consume in the evening. The control group received no intervention.

Main outcome variables

Depression score; Total antioxidant capacity ; Malondialdehyde ; Triglyceride ; Total cholesterol ; HDL-C ; LDL-C ; Fasting Blood Sugar; Insulin; Insulin resistance; weight; Body-mass index.

General information

Reason for update

Correction of sampling date

Acronym

IRCT registration information

IRCT registration number: **IRCT20191109045383N1**
Registration date: **2019-11-16, 1398/08/25**
Registration timing: **retrospective**

Last update: **2020-04-13, 1399/01/25**
Update count: **1**

Registration date

2019-11-16, 1398/08/25

Registrant information

Name
Maryam Abedini
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-14, 1397/01/25

Expected recruitment end date
2019-03-03, 1397/12/12
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The Effect Of Concentrated Pomegranate Juice On Depression score , Insulin Resistance(HOMA-IR) , oxidative And Antioxidant Markers (TAC , MDA) In Women With Polycystic Ovary Syndrome(PCOS)

Public title
The effect of pomegranate juice concentrate in women with polycystic ovary syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
18≤Age≤40 BMI ≥ 25 Being single Not having acute and chronic diseases such as: cardiovascular disease, kidney, liver, diabetes, hypothyroidism, hyperthyroidism, asthma, neoplastic, hyperprolactinemia, malabsorption disorders, hypertension, dyslipidemia, (new or during 6 months). No Depression Not following a specific diet. Not following a specific exercise program. Non-use of drugs such as contraceptive pills (Oral contraceptive pill), hormonal drugs, anti-diabetic drugs, anti-obesity drugs, antioxidant supplements and multivitamin minerals, blood lipid lowering drugs. Not smoking Not allergic to pomegranate and its products. Not consuming pomegranates and pomegranate-containing products at least 2 months before starting the study
Exclusion criteria:
Pregnancy Not consuming Concentrated Pomegranate Juice completely Not willing to continue participating in the study
Age
From **18 years** old to **40 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **44**
Randomization (investigator's opinion)
Randomized
Randomization description
First, we select all individuals using available sampling method and after describing the aims and methods of the study, if they wish to participate in the study, we randomly divided them into two groups of Concentrated pomegranate juice and control.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Other
Other design features
In this study, all individuals are divided into two groups: the first group receives the intervention and the second group is the control group that receives no intervention.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Faculty of Nutrition, Isfahan University of Medical Sciences, Hezar Jarib Ave., Isfahan, Iran
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2018-03-04, 1396/12/13
Ethics committee reference number
396806

Health conditions studied

1

Description of health condition studied
Polycystic Ovary Syndrome
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Evaluation of malondialdehyde in women with polycystic ovary syndrome
Timepoint
Baseline and 8 weeks after starting the study
Method of measurement
Measurement of serum malondialdehyde by calorimetric method using kiazist kit

Secondary outcomes

1

Description

Evaluation of total antioxidant capacity in women with polycystic ovary syndrome

Timepoint

Baseline and 8 weeks after starting the study

Method of measurement

Measurement of serum total antioxidant capacity by cupric reducing antioxidant capacity (CUPRAC) method using kiazist kit

2

Description

Evaluation of insulin resistance in women with polycystic ovary syndrome

Timepoint

Baseline and 8 weeks after starting the study

Method of measurement

Measurement of Insulin Resistance Using Formula (fasting plasma glucose (mMol/L) × insulin (µIU/mL))/22.5. The levels of serum insulin will be determined using ELISA kit (AccuBind, Monobind Inc., USA) and fasting blood sugar will be measured by enzymatic photometric method using standard kits (Pars Azmun, Tehran, Iran).

3

Description

Depression score

Timepoint

Baseline and 8 weeks after starting the study

Method of measurement

Depression Anxiety Stress Scale-21 (DASS-21) questionnaire

Intervention groups

1

Description

Intervention group: 45 ml Concentrated Pomegranate Juice for 8 weeks with 180 cc water, in the afternoon, Takeda factory of East Azarbaijan .

Category

Treatment - Other

2

Description

Control group: Does not receive any intervention.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Clinic

Full name of responsible person

Maryam Abedini

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Shahid Beheshti Clinic, Metal Bridge, Isfahan, Iran, ,

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

shaghayegh haghjoo

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Maryam Abedini

Position
MSc student
Latest degree
Bachelor
Other areas of specialty/work
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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
Yes - There is a plan to make this available
Title and more details about the data/document
clinical measurements as word file can be shared for other researchers
When the data will become available and for how long
the main data are available one year after pulication
To whom data/document is available
data are available for all clinicians especially RDNs.
Under which criteria data/document could be used
data users had not allowed to analyze this data for drug industries.
From where data/document is obtainable
mail to this address: maryamabedinii93@gmail.com
What processes are involved for a request to access data/document
just mail to this address and request with IRCT-related code: maryamabedinii93@gmail.com
Comments