Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effects of cardamom supplementation on antheropometric indices, cardiometabolic status, obesity and diabetes gene expression among obese women with polycystic ovary syndrome

Protocol summary

Study aim
Effects of cardamom supplementation on anheropometric indices, cardiometabolic status, obesity and diabetes gene expression among obese women with polycystic ovary syndrome

Design
The double blind randomized clinical trial will be performed on 140 women with polycystic ovary syndrome with a body mass index more than 30.

Settings and conduct
This study will be performed on 140 women with polycystic ovary syndrome referred to Motazedi Educational and Medical Center- Kermanshah during 12 weeks. The intervention group will receive 3 grams of cardamom supplement daily. Before and after the intervention of food intake, physical activity, as well as blood pressure, biochemical indices, lipid profile, sexual hormones, obesity and diabetes genes will be taken from the participants.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Diagnosis of polycystic ovary syndrome based on Rotterdam criteria in 18- 45-year-old volunteer women with a body mass index more than 30 kg/ m2 Exclusion criteria: pregnancy, lactation, diseases such as autoimmune, gastrointestinal, liver, thyroid and unstable cardiovascular diseases, severe depression, mental and psychological illness, severe respiratory diseases (asthma and chronic bronchitis), consumption of any vitamin and mineral supplements, allergies to cardamom, cardamom tea and cardamom products

Intervention groups
All participants will be subjected to a weight loss diet, in which case they will lose 500-300 kcal per day of energy required based on the ideal adjusted body weight. Intervention group: 3 grams of cardamom in three doses of one gram with the main meals to reduce possible gastrointestinal complications Control group: Plasbo with the same appearance of intervention supplements and the same hours of consumption

Main outcome variables
Anthropometric and cardio-metabolic indices, obesity and diabetes gene

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200608047697N1**
Registration date: **2020-08-01, 1399/05/11**
Registration timing: **prospective**

Last update: **2020-08-01, 1399/05/11**
Update count: **0**

Registration date
2020-08-01, 1399/05/11

Registrant information

Name
Shima Moradi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 83 3710 2015

Email address
shima.moradi@kums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-08-21, 1399/05/31

Expected recruitment end date
2020-11-19, 1399/08/29

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effects of cardamom supplementation on antheropometric indices, cardiometabolic status, obesity and diabetes gene expression among obese women with polycystic ovary syndrome

Public title
Evaluation of effects of cardamom supplementation among obese women with polycystic ovary syndrome
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of polycystic ovary syndrome based on Rotterdam criteria for at least two of the following factors: 1. Oligomnorrhea or amenorrhea. 2. Biochemical or clinical symptoms increased levels of androgens in the blood.3- Having polycystic ovaries in ultrasound Women with age range between 18-45 year Body mass index more than 30 kg/m2 Voluntary participation in the project
Exclusion criteria:
Pregnancy and lactation Illnesses such as autoimmune, gastrointestinal, liver, thyroid and unstable cardiovascular diseases, severe depression, mental diseases, severe respiratory diseases (asthma and chronic bronchitis) Take any vitamin and mineral supplements Allergies to cardamom, cardamom tea and cardamom products
Age
From **18 years** old to **45 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **140**
Randomization (investigator's opinion)
Randomized
Randomization description
Using the draw method the names of the participants will be written on the separate papers and will be placed inside a container. Then the names of the participants will be withdrawn randomly. The first 70 names will be placed in the intervention group and the rest in the control group.
Blinding (investigator's opinion)
Double blinded
Blinding description
This clinical trial will be double blind, with the researcher and participants not aware of the allocation of groups, and the supplements appearance will be similar in both groups. The supplements will be encode by manufacturer before delivery.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Kermanshah University of Medical Sciences
Street address
Building No. 2, Research Council of Kermanshah University of Medical Sciences (KUMS), Shahid Beheshti Boulevard, Kermanshah, Iran.
City
Kermanshah
Province
Kermanshah
Postal code
6719851351
Approval date
2020-07-13, 1399/04/23
Ethics committee reference number
IR.KUMS.REC.1399.375

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
Reducing of weight among obese women with polycystic ovary syndrome
Timepoint
Measurement of weight before intervention and 12 week after intervention
Method of measurement
Weight measurement will be performed using the Inbody 770 with minimal clothing.

2

Description
Reducing of waist circumference among obese women with polycystic ovary syndrome
Timepoint
Measurement of waist circumference before intervention and 12 week after intervention
Method of measurement
Waist circumference measurement will be performed using a flexible tape between the last rib and the top of the iliac crest in exhalation.

3

Description
Improvement of blood pressure among obese women with polycystic ovary syndrome
Timepoint
Measurement of blood pressure before intervention and 12 week after intervention
Method of measurement
Blood pressure will be measured using a digital arm sphygmomanometer.

4

Description
Improvement of insulin level
Timepoint
Measurement of insulin level before intervention and 12 week after intervention
Method of measurement
Insulin level will be measured by ELISA method.

5

Description
Improvement of fasting blood sugar
Timepoint
Measurement of fasting blood sugar before intervention and 12 week after intervention
Method of measurement
Fasting blood sugar was measured by Glucose oxidase method.

6

Description
Improvement of lipid profile
Timepoint
Measurement of lipid profile before intervention and 12 week after intervention
Method of measurement
Lipid profile will be measured by enzymatic kits (Pars Azmoon, Iran).

7

Description
Improvement of inflammatory status
Timepoint
Measurement of C- reactive protein before intervention and 12 week after intervention
Method of measurement
Measurement of C- reactive protein will be performed by Highly sensitive CRP assay method.

8

Description
Reducing of obesity and diabetes gene expression
Timepoint
Measurement of obesity and diabetes gene expression before intervention and 12 week after intervention
Method of measurement
The expression of obesity and diabetes genes will be determined by Real Time PCR and specific primers designed with valid software.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention will be performed with weight loss diet (reduction of 300-500 kcal per day of energy required based on the adjusted ideal body weight) and three 1 gram capsules containing cardamom daily (Karen Company, Canada, representative in Iran) three times a day with the main meals.
Category
Treatment - Drugs

2

Description
Control group: weight loss diet (reduction of 300-500 kcal per day of energy required based on the adjusted ideal body weight) and three 1 gram capsules containing starch (placebo) (Karen Company, Canada, representative in Iran) will be received three times a day with the main meals.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Motazedi Educational and Medical Center
Full name of responsible person
Shima Moradi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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
Kermanshah 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
Kermanshah University of Medical Sciences
Full name of responsible person
Shima Moradi
Position
Academic researcher
Latest degree
Master
Other areas of specialty/work
Nutrition
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Person responsible for updating data

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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
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Data collected for the primary outcomes will be shared.
When the data will become available and for how long
After publication of the results in valid Journals
To whom data/document is available
The data will only be available for people working in academic institutions.
Under which criteria data/document could be used
For Meta- analysis studies
From where data/document is obtainable
Shima Moradi- Shool of nutritional Sciences and Food Technology Shima.Moradi@kums.ac.ir
What processes are involved for a request to access data/document
By email Shima.Moradi@kums.ac.ir
Comments