

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Oct 2023

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

Protocol summary

Study aim

Effects of cardamom supplementation on anthropometric 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: Placebo 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 anthropometric 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. Oligomenorrhea 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

Street address

Kermanshah, Ferdowsi Sq.Motazedi Educational and Medical Center

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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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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