

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 2026

### 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/ m<sup>2</sup>  
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/m<sup>2</sup> 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

##### **City**

Kermanshah

##### **Province**

Kermanshah

**Postal code**  
6718814474  
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motazedihospital.kermanshah@gmail.com  
**Web page address**  
<https://motazedi.kums.ac.ir/fa/ipd/ipd/us>

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Kermanshah University of Medical Sciences  
**Full name of responsible person**  
Prof. Farid Najafi  
**Street address**  
Building No. 2, Research Council Kermanshah  
University of Medical Sciences (KUMS), Shahid  
Beheshti Boulevard, Kermanshah, Iran.  
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**Province**  
Kermanshah  
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6715847141  
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**Email**  
fnajafi@kums.ac.ir

#### 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

#### Street address

Isar Square, next to Farabi Hospital, School of  
Nutrition and Food Sciences

#### City

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#### Province

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#### Postal code

6719851351

#### Phone

+98 83 3710 2015

#### Email

Shima.Moradi@kums.ac.ir

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Kermanshah University of Medical Sciences  
**Full name of responsible person**  
Dr. Yahya Pasdar  
**Position**  
Associate Professor  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Nutrition  
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Yahya.Pasdar@kums.ac.ir

## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Kermanshah University of Medical Sciences  
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Shima Moradi  
**Position**  
Academic Researcher  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Nutrition  
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**Province**

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**Postal code**

6719851351

**Phone**

+98 83 3710 2015

**Email**

Shima.Moradi@kums.ac.ir

**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**