

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### The effect of Cardamom supplementation on serum lipids, glycemic indices and blood pressure in overweight and obese prediabetic women

#### Protocol summary

##### Summary

(1) Objectives: The effect of Cardamom supplementation on serum lipids, glycemic indices and blood pressure in overweight and obese pre diabetic women, (2) Design: This study is a randomized double blind clinical trial, (3) Setting and conduct: People selected from pre diabetic women referred to the tow health centers of Karaj city after getting a written informed consent and considering the inclusion and exclusion criteria, (4) Participants including major eligibility criteria: - Inclusion criteria: Having at least one of this criteria, FBS; 100-125 mg/dl, HbA1C: 5.7-6.4, 2hpp blood glucose: 140-199 mg/dl; Age: 30-70 years; BMI: 25-39.9 kg/m<sup>2</sup>; Having at least one of the following criteria: TG>150 mg/dl, Chol>200 mg/dl, LDL>100 mg/dl, HDL<50 mg/dl. -Exclusion criteria: Multi vitamin and anti oxidant supplements consumption during the intervention; Changes in diet or physical activity; Not intaking of more than 10% of supplements; Morbidity to diabetes during the intervention, (5) Intervention: 80 subjects randomly assign to tow groups (40 intervention and 40 control groups). Intervention group receives 3 gr of green cardamom daily and placebo group receives 3 gr of rusk powder from 3 capsules (1 gr) tree times a day with meals. Period of intervention is 2 months, (6) main outcome measures (variables): Anthropometric measurements are performed by standard methods. Systolic and diastolic blood pressure are measured before and after the intervention in fasting state. Blood sample is taken from patient and FBS, TG, total Chol, HDL and insulin is measured before and after the study. General questionnaire, 24h dietary recall and physical activity questionnaire (IPAQ short form) are completed before and after the intervention. People are followed up by phone each week. The study compliance will be assumed through counting consumed capsules.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014060817254N2**

Registration date: **2014-09-02, 1393/06/11**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2014-09-02, 1393/06/11

##### Registrant information

##### Name

Gity Sotoude

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4293 3333

##### Email address

gsotodeh@tums.ac.ir

##### Recruitment status

##### Recruitment complete

##### Funding source

Vice chancellor for research, Tehran University of Medical Sciences Vice chancellor for research, Tehran University of Medical Sciences, The 5th floor, Qods St, Keshavarz Blvd , Tehran

##### Expected recruitment start date

2013-03-20, 1391/12/30

##### Expected recruitment end date

2014-03-20, 1392/12/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

## Trial completion date

empty

## Scientific title

The effect of Cardamom supplementation on serum lipids, glycemic indices and blood pressure in overweight and obese prediabetic women

## Public title

The effect of Cardamom supplementation on serum lipids, glucose and blood pressure in prediabetic women

## Purpose

Prevention

## Inclusion/Exclusion criteria

Inclusion criteria: Prediabetic women with one of the following criteria: FBS; 100-125 mg/dl, HbA1C: 5.7-6.4, 2hpp blood glucose: 140-199 mg/dl; Age: 30-70 years; BMI: 25-39.9 kg/m<sup>2</sup>; Having at least one of the following criteria: TG>150 mg/dl, Chol>200 mg/dl, LDL>100 mg/dl, HDL<50 mg/dl; Willingness to participate in the study. Not included in the study: BMI<25 kg/m<sup>2</sup> or BMI≥40 kg/m<sup>2</sup>; Following a specific diet for last three months; Professional athlete; Sensitivity to Cardamom (allergy); Pregnancy and lactation; Nutritional supplement and multi vitamin-mineral consumption at least 2 times a week in the last month; Medical history of gastrointestinal ulcers, kidney or gall stones; Medical history of coronary heart disease, cancer and MS; Blood pressure>130/80 mmHg; LDL>160 mg/dl; TG>300 mg/dl. Exclusion criteria: Multi vitamin and anti oxidant supplements consumption during the intervention; Changes in diet or physical activity; Not intaking of more than 10% of supplements; Morbidity to diabetes during the intervention.

## Age

From **30 years** old to **70 years** old

## Gender

Female

## Phase

2-3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **80**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Tehran University of Medical Sciences

##### Street address

6th floor, the main organization of Tehran University of Medical sciences, at the corner of Qods Stt, Keshvarz Blv

##### City

Tehran

##### Postal code

##### Approval date

2014-07-26, 1393/05/04

##### Ethics committee reference number

93-01-161-25470-117279

## Health conditions studied

### 1

#### Description of health condition studied

Pre diabetes

#### ICD-10 code

R73.0

#### ICD-10 code description

Impaired glucose tolerance Prediabetes

## Primary outcomes

### 1

#### Description

Serum Triglycerid

#### Timepoint

before and after the intervention

#### Method of measurement

Enzymatic Measurement of fasting Serum Triglycerid by using kits

### 2

#### Description

Serum LDL

#### Timepoint

before and after the intervention

#### Method of measurement

Enzymatic Measurement of fasting serum LDL by using kits

### 3

#### Description

Fasting blood sugar

#### Timepoint

before and after the intervention

#### Method of measurement

Enzymatic Measurement of fasting blood sugar by using kits

## 4

### **Description**

Serum cholesterol

### **Timepoint**

before and after the intervention

### **Method of measurement**

Enzymatic Measurement of fasting serum cholesterol by using kits

## 5

### **Description**

Serum HDL

### **Timepoint**

before and after the intervention

### **Method of measurement**

Enzymatic Measurement of fasting serum HDL by using kits

## 6

### **Description**

Serum insulin concentration

### **Timepoint**

before and after the intervention

### **Method of measurement**

Enzymatic Measurement of serum insulin concentration by using kits

## 7

### **Description**

Insulin sensitivity

### **Timepoint**

before and after the intervention

### **Method of measurement**

QUIKI formula

## 8

### **Description**

Insulin Resistance

### **Timepoint**

before and after the intervention

### **Method of measurement**

HOMA-IR formula

## 9

### **Description**

Systolic blood pressure

### **Timepoint**

before and after the intervention

### **Method of measurement**

Measured with a manometer

## 10

### **Description**

Diastolic blood pressure

### **Timepoint**

before and after the intervention

### **Method of measurement**

Measured with a manometer

## **Secondary outcomes**

### 1

#### **Description**

Weight

#### **Timepoint**

before and after the intervention

#### **Method of measurement**

Measured with a digital scale

### 2

#### **Description**

BMI

#### **Timepoint**

before and after the intervention

#### **Method of measurement**

Measured with formula

### 3

#### **Description**

Waist circumference

#### **Timepoint**

before and after the intervention

#### **Method of measurement**

measurement with a meter

## **Intervention groups**

### 1

#### **Description**

group receiving green cardamom :capsules containing 1g cardamom, three a day for 2 month

#### **Category**

Other

### 2

#### **Description**

placebo group receiving rusk powder: capsules containing 1g of rusk powder, three a day for 2 month

#### **Category**

Placebo

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Health centers Imam Hussein

##### **Full name of responsible person**

Fatemeh Yaghooblou

##### **Street address**

104 St, Emam khomeini Blv, Mohammadshahr, Karaj

##### **City**

Karaj

## 2

### Recruitment center

**Name of recruitment center**

Health Centers Vali-Asr

**Full name of responsible person**

Fatemeh Yaghooblou

**Street address**

Golestan 20 Alley, Anbar naft St, Malard Road, Karaj

**City**

Karaj

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vice chancellor for research, Tehran University of Medical Sciences

**Full name of responsible person**

Dr. Yunesian

**Street address**

Vice chancellor for research, Tehran University of Medical Sciences, The 5th floor, Qods St, Keshavarz Blvd, Tehran

**City**

Tehran

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research, Tehran University of Medical 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**

Tehran university of Medical Sciences

**Full name of responsible person**

Fatemeh Yaghooblou

**Position**

Student in MSPH

**Other areas of specialty/work****Street address**

No 44, Hojjat doost St, Naderi St, Keshavarz Blv, School of Nutritional Sciences and Dietetic, Tehran, Iran.

**City**

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**Postal code****Phone**

+98 26 3451 4381

**Fax****Email**

yaghooblou.fatemeh@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tehran university of Medical Sciences

**Full name of responsible person**

Dr. Sotoude

**Position**

PhD of Nutrition sciences

**Other areas of specialty/work****Street address**

No 44, Hojjat doost St, Naderi St, Keshavarz Blv, School of Nutritional Sciences and Dietetic, Tehran, Iran.

**City**

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+98 21 8895 5118

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gsotodeh@tums.ac.ir

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Tehran university of Medical Sciences, School of Nutritional Sciences and Dietetic

**Full name of responsible person**

Dr. Sotoude

**Position**

PhD of Nutrition sciences

**Other areas of specialty/work****Street address**

No 44, Hojjat doost St, Naderi St, Keshavarz Blv, School of Nutritional Sciences and Dietetic, Tehran, Iran.

**City**

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+98 21 8895 5118

**Fax****Email**

gsotodeh@tums.ac.ir

**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*