# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 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/m2; 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/m2; 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/m2 or BMI≥40 kg/m2; 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**

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## Person responsible for scientific inquiries

**Contact**

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**Full name of responsible person**
Dr. Sotoude

**Position**
PhD of Nutrition sciences

**Other areas of specialty/work**

**Street address**
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## Person responsible for updating data

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

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**Position**
PhD of Nutrition sciences

**Other areas of specialty/work**

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**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*