

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effect of cardamom supplementation on blood oxidative stress status and inflammatory factors in overweight and obese prediabetic women

Protocol summary

Summary

(1) Objectives: The effect of cardamom supplementation on blood oxidative stress status and inflammatory factors in overweight and obese prediabetic 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 GR, SOD, Total Antioxidant Capacity, MDA, Protein Carbonyl, IL-6, hs-CRP and TNF- α 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: **IRCT2015042917254N3**

Registration date: **2015-05-09, 1394/02/19**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-05-09, 1394/02/19

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 blood oxidative stress status and inflammatory factors in overweight and obese prediabetic women

Public title

The effect of cardamom supplementation on blood oxidative stress status and inflammatory factors 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; Smoking. 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

GR activity

Timepoint

before and after the intervention

Method of measurement

Enzymatic Measurement of fasting GR activity by using kits

2

Description

SOD activity

Timepoint

before and after the intervention

Method of measurement

Enzymatic Measurement of fasting SOD activity by using kits

3

Description

Serum Total Antioxidant Capacity

Timepoint

before and after the intervention

Method of measurement

Enzymatic Measurement of Serum Total Antioxidant Capacity by using kits

4

Description

MDA Concentration

Timepoint

before and after the intervention

Method of measurement

Enzymatic Measurement of fasting MDA Concentration by using kits

5

Description

Protein Carbonyl Concentration

Timepoint

before and after the intervention

Method of measurement

Enzymatic Measurement of fasting Protein Carbonyl Concentration by using kits

6

Description

IL-6 Concentration

Timepoint

before and after the intervention

Method of measurement

Enzymatic Measurement of fasting IL-6 Concentration by using kits

7

Description

hs-CRP Concentration

Timepoint

before and after the intervention

Method of measurement

Enzymatic Measurement of fasting hs-CRP Concentration by using kits

8

Description

TNF- α Concentration

Timepoint

before and after the intervention

Method of measurement

Enzymatic Measurement of fasting TNF- α Concentration by using kits

Secondary outcomes

1

Description

Waist circumference

Timepoint

before and after the intervention

Method of measurement

measurement with a meter

2

Description

BMI

Timepoint

before and after the intervention

Method of measurement

Measured with formula

3

Description

Weight

Timepoint

before and after the intervention

Method of measurement

Measured with a digital scale

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

Tehran

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

Tehran

Postal code**Phone**

+98 21 8895 5118

Fax**Email**

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

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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