

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

The effects of green cardamom supplementation on blood pressure and endothelium function, blood glucose indices, lipids, oxidant and anti oxidant parameters, sirtuin-1, irisin, oxidised LDL, apolipoprotein A1 and B and paraoxonase in type 2 diabetic patients

Protocol summary

Study aim

This study aimed to determine the effects of green cardamom supplementation on blood pressure and endothelium function, blood glucose indices, lipids, oxidant and anti oxidant parameters, sirtuin-1, irisin, oxidised LDL, apolipoprotein A1, B and paraoxonase in type 2 diabetic patients.

Design

The 83 participants were recruited from the Diabetes Research Center, Endocrinology and Metabolism Clinical Sciences Institute. A total of 83 eligible participants were randomized into two groups using block randomization method. Stratified randomization was used to match participants based on gender (male/female) and BMI (25-29.9/ 30-34.9 kg/m²) into 4 block sizes

Settings and conduct

The participants were recruited from the Diabetes Research Center, Endocrinology and Metabolism Clinical Sciences Institute, Tehran University of Medical Sciences..

Participants/Inclusion and exclusion criteria

patients aged between 30 to 60 years of age with a body mass index (BMI) 25-34.9 kg/m², and HbA1C value higher than 7% were recruited for this study. The patients should have been diagnosed at least 2 years prior to the study.

Intervention groups

intervention (Cardamom) and placebo (rusk powder) group.

Main outcome variables

determine the effects of green cardamom supplementation on blood pressure and endothelium function, blood glucose indices, lipids, oxidant and anti oxidant parameters, sirtuin-1, irisin, oxidised LDL, apolipoprotein A1, B and paraoxonase in type 2 diabetic patients.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT2016042717254N5**

Registration date: **2016-11-23, 1395/09/03**

Registration timing: **registered_while_recruiting**

Last update: **2019-08-26, 1398/06/04**

Update count: **1**

Registration date

2016-11-23, 1395/09/03

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

Expected recruitment start date

2016-11-20, 1395/08/30

Expected recruitment end date

2017-03-20, 1395/12/30

Actual recruitment start date

2016-11-20, 1395/08/30

Actual recruitment end date

2017-07-20, 1396/04/29

Trial completion date

2017-07-20, 1396/04/29

Scientific title

The effects of green cardamom supplementation on blood pressure and endothelium function, blood glucose indices, lipids, oxidant and anti oxidant parameters, sirtuin-1, irisin, oxidised LDL, apolipoprotein A1 and B and paraoxonase in type 2 diabetic patients

Public title

The effects of green cardamom supplementation in type 2 diabetic patients

Purpose

Health service research

Inclusion/Exclusion criteria**Inclusion criteria:**

Inclusion criteria Men and women between the age of 30–60 years old who have confirmed diagnosis of type 2 diabetes for more than 2 years; last HbA1C value greater than 7 %; Body Mass Index (BMI) between 25 and 35 kg/m²; Lipid-lowering drugs more than 3 months

Exclusion criteria:

Exclusion criteria Patients with any of the following criteria will be excluded: being on insulin regimen; use of fibrat (PPAR alpha ligand); TZD (PPAR gamma ligand); Smoking or alcohol consumption at least once a week in the past month; consumption of (at least once a week) herbal supplements; antioxidant; Multivitamin-Mineral in the past 3 months; pregnant and lactating women; have any gastrointestinal disorder, hepatic or renal disease, inflammatory disease, thyroid problems; any change in diet during the past 3 months, Consumers of anticoagulants (warfarin, heparin), antiplatelet drugs (Plavix), suppressor CNS (benzodiazepines), barbiturates (phenobarbital), antidepressants.

Age

From **30 years** old to **59 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **80**

Actual sample size reached: **83**

Randomization (investigator's opinion)

Randomized

Randomization description

Using block randomization method, in which the assignment was done based on sex (male/female) and BMI (overweight/ obese). By using stratified randomization participants were matched based on sex and BMI into blocks. Therefore, the block size was 4. By using this method equal number of men and women as well as overweight and obese patients were assigned to green cardamom and rusk powder group. Random

allocation sequence was generated by using Random allocation software: RAS. The allocation process of participants into cardamom and rusk powder groups was done by a third person who was not involved in the project directly.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study is a randomized, double-blind, placebo controlled clinical trial. The capsules were labeled as A or B to be delivered to the subjects by a third person who was not involved in the project directly and had the job to make the supplements. All placebo capsules were placed close to cardamom capsules to take cardamom smell. For doing this, the supplements were safely capsulated. Then a person who was not involved in the study, packaged the two types of supplements in the plastic bags and placed them close together in a covered box. After one week the capsules were packaged in the small containers to be delivered to the subjects. It was tested to see if the placebo capsules took the smells.

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

First of Qods, Keshavarz Beulvard

City

tehran

Province

Tehran

Postal code

14155-6117

Approval date

2015-12-13, 1394/09/22

Ethics committee reference number

IR.TUMS.REC.1394.1388

Health conditions studied**1****Description of health condition studied**

diabetes

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

FBS

Timepoint

Before intervention, after intervention

Method of measurement

KIT

2

Description

FPI

Timepoint

Before intervention, after intervention

Method of measurement

KIT

3

Description

Hg A1c

Timepoint

Before intervention, after intervention

Method of measurement

kit

4

Description

lipid profile

Timepoint

Before intervention, after intervention

Method of measurement

kit

5

Description

TAC

Timepoint

Before intervention, after intervention

Method of measurement

kit

6

Description

SOD

Timepoint

Before intervention, after intervention

Method of measurement

kit

7

Description

GPx

Timepoint

Before intervention, after intervention

Method of measurement

kit

8

Description

MDA

Timepoint

Before intervention, after intervention

Method of measurement

kit

9

Description

Sirt1

Timepoint

Before intervention, after intervention

Method of measurement

kit

10

Description

Irisin

Timepoint

Before intervention, after intervention

Method of measurement

kit

11

Description

VCAM

Timepoint

Before intervention, after intervention

Method of measurement

Kit

12

Description

CD-163

Timepoint

Before intervention, after intervention

Method of measurement

kit

13

Description

ADMA

Timepoint

Before intervention, after intervention

Method of measurement

Kit

14

Description

SBP

Timepoint

Before intervention, middle of intervention, after intervention

Method of measurement

mmhg by mercury manometer

15

Description

OX-LDL

Timepoint

Before intervention, after intervention

Method of measurement

KIT

16

Description

PON

Timepoint

Before intervention, after intervention

Method of measurement

KIT

17

Description

apo A1 - apo B

Timepoint

Before intervention, after intervention

Method of measurement

KIT

18

Description

ICAM

Timepoint

Before intervention, after intervention

Method of measurement

Kit

19

Description

NO

Timepoint

Before intervention, after intervention

Method of measurement

Kit

20

Description

TNF-alfa

Timepoint

Before intervention, after intervention

Method of measurement

Kit

21

Description

IL-6

Timepoint

Before intervention, after intervention

Method of measurement

Kit

22

Description

hsCRP

Timepoint

Before intervention, after intervention

Method of measurement

Kit

23

Description

DBP

Timepoint

Before intervention, middle of intervention, after intervention

Method of measurement

mmhg by mercury manometer

Secondary outcomes

empty

Intervention groups

1

Description

Green cardamom supplements are prepared as 0.5 gram capsules. 2 capsule per meal (3 gram daily) should be consumed for 10 weeks

Category

Placebo

2

Description

placebo (flour breadcrumbs) supplements are prepared as 0.5 gram capsules. 2 capsule per meal (3 gram daily) should be consumed for 10 weeks

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati hospital endocrine clinic

Full name of responsible person

Dr. Ensieh Nasli-Esfahani

Street address

خ امير آباد

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Tehran

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Tehran

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000000000

Phone

+98 21 8894 5247

Email

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mrs. Rostamabadi

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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

Tehran 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

Nutrition and Dietetics Faculty of Tehran Medical Sciences

Full name of responsible person

Gity Sotoudeh

Position

PhD in Nutritional Sciences

Latest degree

Ph.D.

Other areas of specialty/work

Medical Education

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Gity Sotoudeh

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Person responsible for updating data

Contact

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Latest degree

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Other areas of specialty/work

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gsotodeh@tums.ac.ir

Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Yes - There is 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

No decision has been made in this case

When the data will become available and for how long

access to data few months after results are published

To whom data/document is available

Data are available for researchers

Under which criteria data/document could be used

If Data are available it would be available for researchers

From where data/document is obtainable

Dr. Gity Sotoudeh

What processes are involved for a request to access data/document

No decision has been made in this case

Comments