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)
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+98 21 4293 3333
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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

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Person responsible for scientific inquiries

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PhD of Nutrition sciences

Other areas of specialty/work

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Person responsible for updating data

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Full name of responsible person
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Other areas of specialty/work

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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