

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Aug 2026

Effect of green coffee extract supplementation on glycemic control, insulin resistance, lipid profile, advanced glycation end products, inflammatory and oxidant status in overweight/obese patients with type 2 diabetes : a randomized double-blind clinical trial

Protocol summary

Study aim

Effect of green coffee extract supplementation on glycemic control, insulin resistance, lipid profile, advanced glycation end products, inflammatory and oxidant status in overweight/obese patients with type 2 diabetes

Design

Clinical trial with control group, with parallel group, double blind, randomised, on 44 patients with type 2 diabetes

Settings and conduct

In this study, 44 patients with type 2 diabetes will be select in Taleghani hospital then they divide in two groups (intervention and placebo group). They will be followed up for 10 weeks. All group allocation is blind for the investigators and subjects

Participants/Inclusion and exclusion criteria

Inclusion criteria: subjects aged 35-70 years old; no specific diet; body mass index 25-35 kg/m². Exclusion criteria: hepatic and renal; taking antioxidants and multivitamins-minerals supplementation.

Intervention groups

In the intervention group, subjects receive green coffee extract supplementation In the control group, subjects receive placebo

Main outcome variables

Blood glucose and insulin Triglycerides, low density lipoprotein, high density lipoprotei, total cholesterol Carboxymethyl lysine Malondialdehyde High-sensitivity C-reactive Protein

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090203001640N18**

Registration date: **2020-06-14, 1399/03/25**

Registration timing: **prospective**

Last update: **2020-06-14, 1399/03/25**

Update count: **0**

Registration date

2020-06-14, 1399/03/25

Registrant information

Name

Parvin Mirmiran

Name of organization / entity

Obesity Research Center, Research Institute for Endocrine Sciences, Shahid Beheshti University of Me

Country

Iran (Islamic Republic of)

Phone

+98 21 2243 2500

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mirmiran@endocrine.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-15, 1399/06/25

Expected recruitment end date

2021-03-15, 1399/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of green coffee extract supplementation on glycemic control, insulin resistance, lipid profile, advanced glycation end products, inflammatory and oxidant status in overweight/obese patients with type 2 diabetes : a randomized double-blind clinical trial

Public title

Effect of green coffee extract supplementation in patients with type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Agreement to participate in the study and completing informed consent form
Subjects aged 35-70 years old
Body mass index between 25-35 kg/m²
Fasting blood glucose $\geq$ 126 mg/dl or 2-h plasma glucose $\geq$ 200 mg/dl or treatment with anti-hyperglycemic medications

Exclusion criteria:

Following any specific diet in past three months
Pregnant and lactating women
Insulin treatment

Age

From **35 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Random assignment to intervention and control groups
Participants were randomly assigned to intervention or control group in the random blocks based on the random number table. The sequence of permuted blocks was generated with a random number table. An individual with no clinical involvement in the trial, put the label of intervention or control group in an opaque and sealed envelope based on the random sequence. Then the other person, who was not aware of random sequences and the envelope content, assigned the patients to the intervention or control group.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is designed as a double blind study. The subjects, main investigator and outcome assessor are not aware of each patient's treatment assignment and the main investigator is not involved in the randomization process.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

national nutrition and food technology research institute

Street address

No. 7, Shahid Hafezi Ave, Shahid frahzadi Blv, Tehran

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Postal code

1985717413

Approval date

2020-05-13, 1399/02/24

Ethics committee reference number

IR.SBMU.NNFTRI.REC.1399.007

Health conditions studied

1

Description of health condition studied

Type 2 diabetes

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes

1

Description

Fasting blood glucose

Timepoint

At the beginning and end of the study

Method of measurement

Enzymatic /kit

2

Description

Plasma insulin

Timepoint

At the beginning and end of the study

Method of measurement

ELISA

3

Description

Plasma triglyceride

Timepoint

At the beginning and end of the study

Method of measurement

Enzymatic /kit

4

Description

Malondialdehyde

Timepoint

At the beginning and end of the study

Method of measurement

Colorimetric

5

Description

Carboxymethyl lysine

Timepoint

At the beginning and end of the study

Method of measurement

ELISA

6

Description

High-sensitivity C-reactive protein

Timepoint

At the beginning and end of the study

Method of measurement

ELISA

Secondary outcomes

1

Description

Body mass index

Timepoint

At the beginning and end of the study

Method of measurement

Weight in kilograms divided by height in meters squared

2

Description

Systolic blood pressure

Timepoint

At the beginning and end of the study

Method of measurement

Mercury sphygmomanometer

3

Description

Diastolic blood pressure

Timepoint

At the beginning and end of the study

Method of measurement

Mercury sphygmomanometer

Intervention groups

1

Description

Intervention group: Received 400 mg green coffee supplement two times a day orally for two months

Category

Treatment - Other

2

Description

Control group: Placebo group: Received 400 mg starch capsule two times a day for two months

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani hospital

Full name of responsible person

Parvin Mirmiran

Street address

Taleghani hospital, Yaman Ave, Erabi Ave, Shahid Chamran Hwy, Tehran Town, Iran

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parvin.mirmiran@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research of Beheshti University of Medical Sciences

Full name of responsible person

Morteza Abdollahi

Street address

No. 7, Shahid Hafezi Ave, Shahid frahzadi Blv, Tehran

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Email

Morabd@yahoo.com

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 of Beheshti University of Medical Sciences

Proportion provided by this source

60

Public or private sector

Private

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**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Parvin Mirmiran

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Position

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Person responsible for updating data**Contact****Name of organization / entity**

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available