Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 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

Email address
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 ≥ 126 mg/dl or 2-h plasma glucose ≥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 lable 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

City

Tehra

Province

Tehran

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
City
Tehran
Province
Tehran
Postal code
1985717413
Phone
+98 21 2243 9982
Email
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
City
Tehran
Province
Tehran
Postal code
1985717413
Phone
+98 21 2235 7483
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

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

City
Tehran

Province
Tehran

Postal code
1985717413

Phone
+98 21 2235 7483

Email
parvin.mirmiran@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Parvin mirmiran

Position
Professor

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Phone
+98 21 2235 7483

Email
parvin.mirmiran@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Parvin Mirmiran

Position
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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