Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

The effect of green coffee supplement on glycemic control, inflammatory index, lipid profile and anthropometry in type 2 diabetic patients

Protocol summary

Study aim
Determining the effect of green coffee supplement on glycemic control, oxidative stress indices, lipid profile and anthropometry in type 2 diabetes

Design
Clinical trial with control group, with parallel groups,single-blind, randomized, phase two on 60 patients, Block Randomization method was used for randomization by Random Allocation Software

Settings and conduct
Patients were selected from Krooni and Mehregan clinicsin Shiraz. demographic information, medical and pharmacological history of individuals along with their height and weight information were recorded. IPAQ and 24-hour food recall questionnaires were taken. 5 cc of blood was also taken. Patients in the intervention group received 800 mg of green coffee extract daily for 8 weeks. Patients in the placebo group also received two placebo tablets daily. At the end of the fourth and eighth weeks,Questionnaires were filled and Blood samples were taken

Participants/Inclusion and exclusion criteria
Inclusion criteria: Definitive diagnosis of type 2 diabetes in a fellow clinician under ADA criteria Age 40 to 69 years Duration of type 2 diabetes is at least 3 years Willingness to participate in the study No allergies to green coffee The type and dose of drugs used in the last 6 months is constant Non-pregnancy and lactation no chronic disease Do not use any dietary supplements in the last 6 months Exclusion criteria: Pregnancy during the study period Changes in medication dosage during the study period Do not take less than 80% of the allocated amount of tablets or do not follow the study design for more than a week

Intervention groups
The intervention group received a green coffee supplement containing 50% chlorine and the control group received a placebo made by the same company with exactly the same appearance.

Main outcome variables
Glycemic status, Inflammatory markers, Oxidative stress, Lipid profile and anthropometry

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200728048232N1**
Registration date: **2020-08-03, 1399/05/13**
Registration timing: **retrospective**

Last update: **2020-08-03, 1399/05/13**
Update count: **0**

Registration date
2020-08-03, 1399/05/13

Registrant information

Name
Zahra Moein jahromi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 3825 2970

Email address
niloufarmoein@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-07-23, 1397/05/01

Expected recruitment end date
2019-04-21, 1398/02/01

Actual recruitment start date
2018-11-22, 1397/09/01

Actual recruitment end date

2019-07-23, 1398/05/01

Trial completion date

2020-01-25, 1398/11/05

Scientific title

The effect of green coffee supplement on glycemic control, inflammatory index, lipid profile and anthropometry in type 2 diabetic patients

Public title

The effect of green coffee supplement on diabetic

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Definitive diagnosis of type 2 diabetes in patients was made by an associate clinical physician under ADA criteria. Duration of type 2 diabetes is at least 3 years The type and dose of drugs used in the last 6 months is constant No chronic (chronic, renal, hepatic, pulmonary, or chronic or acute inflammatory diseases, especially acute inflammation of the pancreas and endocarditis)No heart disease, short bowel syndrome, allergies and thyroid disease Do not use any dietary supplements in the last 6 months No pregnancy and lactation Willingness to participate in the study No allergies to green coffee

Exclusion criteria:

Pregnancy during the study period Changes in medication dosage during the study period Occurrence of one of the above diseases during the study period Dissatisfaction with continuing to participate in the study Do not take less than 80% of the allocated amount of green coffee tablets or do not follow the study design for more than a week

Age

From **40 years** old to **69 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were assigned to one of the intervention and placebo groups based on Block Randomization method by Random Allocation Software

Blinding (investigator's opinion)

Single blinded

Blinding description

By preparing a placebo exactly like the supplement consumed, the participants did not know which of the groups they were in

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

No270.40.Bahonar jonobi

City

shiraz

Province

Fars

Postal code

7177916419

Approval date

2019-01-12, 1397/10/22

Ethics committee reference number

IR.SUMS.REC.1398.585

Health conditions studied

1

Description of health condition studied

diabetes

ICD-10 code

E11.8

ICD-10 code description

Type 2 diabetes mellitus with unspecified complications

Primary outcomes

1

Description

Blood Glu

Timepoint

at the first and end of the study

Method of measurement

Fasting blood glucose by glucose oxidase method

Secondary outcomes

1

Description

weight

Timepoint

First week 4 and week 8 study

Method of measurement

Weight of people in light clothing without shoes and in the fasting state was measured by a digital scale (model

703 Seka) with an accuracy of 100 grams.

2

Description
Insulin sensitivity
Timepoint
at the first and end of the study
Method of measurement
HOMA Homeostasis

3

Description
lipid profile
Timepoint
at the first and end of the study
Method of measurement
Triglycerides, cholesterol and LDL by enzymatic and calorimetric methods using Roach II commercial kits, HDL by calorimetric enzymatic method using Cubas Roach commercial kits

4

Description
insulin sensitivity
Timepoint
at the first and end of the study
Method of measurement
Insulin was evaluated by chemiluminescence method (40). Insulin concentration was determined using the ELISA kit of the American company Monobind. Also, insulin resistance and its components were calculated using the HOMA Homeostasis Model (Index assessment) before and after the intervention as follows: Fasting insulin (microu / L) x fasting glucose (nmol / L) /22.5

5

Description
total antioxidant
Timepoint
at the first and end of the study
Method of measurement
The Ferric Reducing Ability of Plasma method was determined using the main ingredient tripyridyl-S-triazine. Total antioxidant capacity was measured using 40 mM hydrochloric acid, 3-aqueous, 6-aqueous sodium acetate and triazine solution at concentrated Fecl acetic acid at 593 nm.

Intervention groups

1

Description
Intervention group:Take 800 mg of green coffee supplement daily, two 400 mg tablets daily
Category
Treatment - Other

2

Description
Control group: Receive two placebos daily
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Kroni Clinic
Full name of responsible person
Zahra MoeinJahromi
Street address
Shiraz, Kroni region, Kroni clinic
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
no name
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Phone
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Email
info@sums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Zohre mazloom

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Shiraz Razi Blvd. School of Nutrition

City

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Zahra Moein jahromi

Position

MSc student

Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for updating data

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Email

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is 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

Yes - There is 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

Title and more details about the data/document

Part of the data, such as information about the main outcome

When the data will become available and for how long

1399

To whom data/document is available

If a similar study is performed

Under which criteria data/document could be used

evryone

From where data/document is obtainable

Zahra Moin Jahromi 09228031953 Postal code 7177916419

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

send email

Comments