

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jul 2026

The effects of green decaffeinated coffee bean extract on type 2 diabetes mellitus: a randomized, double-blind, placebo-controlled crossover trial

Protocol summary

Summary

Study Objective: The effect of decaffeinated green coffee on type II diabetes. Study design: randomized controlled double blind clinical trial. Study population: Main inclusion criteria: Diagnosis of type II diabetes, aged 45 to 60 years. Main exclusion criteria: Changes in medications or supplements, pregnancy, chronic kidney disease and hepatitis, neuromuscular disease, failure to follow with prescribed diets. Sample size: 50 people in each group, Random allocation will be done by using a table of random numbers. Intervention or interventions study: Decaffeinated Green Coffee Extract Capsules and placebo in terms of appearance is quite similar to drugs but they also contain cellulose. Two capsules per day, a half hour before breakfast, and a half hour before lunch with a glass of water. Intervention time: Phase 1 in two months, a period of two weeks to clean (wash out) and phase 2 in 2 months (4 months). The primary outcome or consequences of the study: weight, systolic blood pressure, diastolic blood pressure, 2hpp, glucose, triglycerides, HDL, waist circumference, LDL, cholesterol.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016052928151N1**

Registration date: **2016-08-15, 1395/05/25**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-08-15, 1395/05/25

Registrant information

Name

Farzad Roshanzamir

Name of organization / entity

Fasa University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3668 8487

Email address

farzadroshanzam@mail.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Fasa University of Medical Sciences Vice chancellor for research, Isfahan University of Medical Sciences

Expected recruitment start date

2016-08-22, 1395/06/01

Expected recruitment end date

2016-09-22, 1395/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of green decaffeinated coffee bean extract on type 2 diabetes mellitus: a randomized, double-blind, placebo-controlled crossover trial

Public title

The effects of decaffeinated green coffee on type II diabetes

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: diagnosis of type II diabetes during the last two years, aged 45 to 60 years, no weight loss during the last 6 months (less than 1 kg), avoiding the use of tobacco and alcohol Exclusion criteria: any change

in medications or supplements, pregnancy, chronic kidney and liver disease, neuromuscular disease, failure to follow the prescribed diet (if food records during the study show the energy intake of 300 calories less or more than the amount specified).

Age

From **45 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Crossover

Other design features

Random allocation will be done by using a table of random numbers.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Fasa University of Medical Sciences

Street address

Ibn sina square, Fasa University of Medical Sciences

City

Fasa

Postal code

Approval date

2016-04-26, 1395/02/07

Ethics committee reference number

IR.FUMS.REC.1394.56

2

Ethics committee

Name of ethics committee

Ethics committee of Fasa University of Medical Sciences

Street address

Ebe sina Square, Fasa University of Medical Sciences

City

Fasa

Postal code

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

IR.FUMS.REC.1394.50

3

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezar Jarib St.

City

Isfahan

Postal code

Approval date

2016-06-19, 1395/03/30

Ethics committee reference number

IR.MUI.REC.1395.3.226

Health conditions studied

1

Description of health condition studied

Type II Diabetes

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

2HPP

Timepoint

Beginning and end of each phase

Method of measurement

Biochemical auto analyzer colorimetric method

2

Description

FBS

Timepoint

Beginning and end of each phase

Method of measurement

Biochemical auto analyzer colorimetric method

3

Description

Weight

Timepoint

Beginning and end of each phase

Method of measurement

Carriage scales

<u>4</u>	
Description	Fetuin-A
Timepoint	Beginning and end of each phase
Method of measurement	ELISA
<u>5</u>	
Description	TG
Timepoint	Beginning and end of each phase
Method of measurement	Biochemical auto analyzer colorimetric method
<u>6</u>	
Description	Chol
Timepoint	Beginning and end of each phase
Method of measurement	Biochemical auto analyzer colorimetric method
<u>7</u>	
Description	LDL
Timepoint	Beginning and end of each phase
Method of measurement	Biochemical auto analyzer colorimetric method
<u>8</u>	
Description	HDL
Timepoint	Beginning and end of each phase
Method of measurement	Biochemical auto analyzer colorimetric method
<u>9</u>	
Description	Insolin
Timepoint	Beginning and end of each phase
Method of measurement	ELISA
<u>10</u>	
Description	HOMA-IR
Timepoint	Beginning and end of each phase
Method of measurement	Formola
<u>11</u>	
Description	GOT
Timepoint	Beginning and end of each phase
Method of measurement	Biochemical auto analyzer colorimetric method
<u>12</u>	
Description	GPT
Timepoint	Beginning and end of each phase
Method of measurement	Biochemical auto analyzer colorimetric method
<u>13</u>	
Description	ALK
Timepoint	Beginning and end of each phase
Method of measurement	Biochemical auto analyzer colorimetric method
<u>14</u>	
Description	Pr
Timepoint	Beginning and end of each phase
Method of measurement	Biochemical auto analyzer colorimetric method
<u>15</u>	
Description	ALB
Timepoint	Beginning and end of each phase
Method of measurement	Biochemical auto analyzer colorimetric method
<u>16</u>	
Description	Total billirobin
Timepoint	Beginning and end of each phase
Method of measurement	Biochemical auto analyzer colorimetric method
<u>17</u>	
Description	Direct billirobin
Timepoint	Beginning and end of each phase
Method of measurement	Biochemical auto analyzer colorimetric method

18

Description

blood pressure

Timepoint

Beginning and end of each phase

Method of measurement

manometer

19

Description

Waist circumference

Timepoint

Beginning and end of each phase

Method of measurement

Meter

20

Description

Polyphenols

Timepoint

Beginning, Middle and end of each phase

Method of measurement

ELISA

21

Description

HbA1C

Timepoint

Beginning and end of each phase

Method of measurement

Biochemical auto analyzer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Each Capsule contains 800 mg of decaffeinated green coffee extract and 50 percent chlorogenic acid . Two Capsules daily, one a half hour before breakfast and another a half hour before lunch with a full glass of water.

Category

Treatment - Drugs

2

Description

Control group: Each Capsule contains 800 mg of cellulose. Two Capsules daily, one a half hour before breakfast and another a half hour before lunch with a full glass of water.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes Clinic

Full name of responsible person

Soheila Ahmadzade

Street address

Shariati Hospital, Fasa

City

Fasa

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Fasa University of Medical Sciences

Full name of responsible person

Zahra Bordbar

Street address

Ebne Sina Squire

City

Fasa

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, Fasa University of Medical Sciences

Proportion provided by this source

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

2

Sponsor

Name of organization / entity

Vice chancellor for research, Isfahan University of Medical Sciences

Full name of responsible person

Nahid Moazam

Street address

Hezar Jarib St.

City

Isfahan

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, Isfahan University of Medical Sciences

Proportion provided by this source**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**

Fasa University of Medical Sciences

Full name of responsible person

Farzad Roshanzamir

Position

PhD Student

Other areas of specialty/work**Street address**

Ibn sina square, Fasa University of Medical Sciences

City

Fasa

Postal code**Phone**

+98 71 5331 6300

Fax**Email**

farzad.roshanzamer@yahoo.com;

froshanzamer@gmail.com;

farzadroshanzam@mail.mui.ac.ir

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

Isfahan University of Medical Sciences

Full name of responsible person

Seyed Moeteza Safavi

Position

PhD

Other areas of specialty/work**Street address**

Hezar Jarib St.

City

Isfahan

Postal code**Phone**

+98 31 3792 3168

Fax**Email**

safavimorteza@nutri.mui.ac.ir

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

Fasa University of Medical Sciences

Full name of responsible person

Farzad Roshanzamir

Position**Other areas of specialty/work****Street address**

Ibn sina square, Fasa University of Medical Sciences

City

Fasa

Postal code**Phone**

+98 71 5333 7816

Fax**Email**

farzad.roshanzamer@yahoo.com;

froshanzamer@gmail.com;

farzadroshanzam@mail.mui.ac.ir

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