Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of green coffee extract supplement on anthropometric indices, lipid profile, oxidized LDL, serum high sensitivity C Reactive Protein and total antioxidant capacity of men with dyslipidemia

Protocol summary

Study aim
The effect of green coffee extract supplement on anthropometric indices, lipid profile, oxidized LDL, serum high sensitivity C Reactive Protein and total antioxidant capacity of men with dyslipidemia

Design
The controlled clinical trials, community-based and action-oriented, parallel group, double-blind, randomized,

Settings and conduct
The study was conducted on men with dyslipidemia in a petrochemical company. The study is a randomized double-blind clinical trial with two groups of drugs and placebo. All participants, researchers, data analyst, and project supervisor are blind.

Participants/Inclusion and exclusion criteria
Entry criteria: 1- Having Dyslipidemia 2- Male 3- Age 25-55 Exit criteria: 1- No use of lipid lowering agent 2- Weight loss diet, vegetarianism, ... 3. No allergy or coffee addiction 4- Reduction or weight gain in 6 months the past

Intervention groups
Drug group: received capsules of green coffee extract. Placebo group: received capsules containing starch.

Main outcome variables
Anthropometric indices, lipid profiles, oxidized LDL, high sensitivity C reactive protein, total antioxidant capacity of serum

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180128038540N1**
Registration date: **2018-09-17, 1397/06/26**
Registration timing: **retrospective**
Last update: **2018-09-17, 1397/06/26**
Update count: **0**

Registration date
2018-09-17, 1397/06/26

Registrant information

Name
Shekoufeh Salamat

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 61 5223 3609

Email address
shekooofeh@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-01-29, 1396/11/09

Expected recruitment end date
2018-01-31, 1396/11/11

Actual recruitment start date
2018-01-29, 1396/11/09

Actual recruitment end date
2018-01-31, 1396/11/11

Trial completion date
2018-03-31, 1397/01/11

Scientific title
The effect of green coffee extract supplement on anthropometric indices, lipid profile, oxidized LDL, serum high sensitivity C Reactive Protein and total antioxidant capacity of men with dyslipidemia

Public title
The effect of green coffee extract on dyslipidemia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

having dyslipidemia male 25to55 age

Exclusion criteria:

Taking lipid lowering drugs weight loss diet vegetarian diet allergy or coffee addiction weight loss or weight gain in the last 6 months

Age

From **25 years** old to **55 years** old

Gender

Male

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **78**

Actual sample size reached: **78**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization was performed using blocked randomization method. Using four blocks of A and B, each person was randomly assigned to one of two placebo or intervention groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

In order to blend, the green tea extract and placebo supplement were named A and B by the company. The randomization was performed using a blocked randomization method. Using four blocks of A and B, each person was randomly assigned to one of two placebo or intervention groups. All participants, researchers, data analyst, and project supervisor are blind.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Golestan' University Blvd.

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Approval date

2018-01-28, 1396/11/08

Ethics committee reference number

IR.AJUMS.REC.1396.899

Health conditions studied

1

Description of health condition studied

Dyslipidemia

ICD-10 code

E78.9

ICD-10 code description

Disorder of lipoprotein metabolism, unspecified

Primary outcomes

1

Description

weight

Timepoint

before and after 8 weeks

Method of measurement

digital scale

2

Description

body fat percentage

Timepoint

before and after 8 weeks

Method of measurement

using body composition analyzer omron BF511

3

Description

Waist circumference

Timepoint

before and after 8 weeks

Method of measurement

using strip meter

4

Description

total cholesterol

Timepoint

before and after 8 weeks

Method of measurement

total cholesterol test on blood sample

5

Description
triglyceride
Timepoint
before and after 8 weeks
Method of measurement
triglyceride test on blood sample

6

Description
low density lipoprotein
Timepoint
before and after 8 weeks
Method of measurement
low density lipoprotein test on blood sample

7

Description
high density lipoprotein
Timepoint
before and after 8 weeks
Method of measurement
high density lipoprotein test on blood sample

8

Description
oxidised low density lipoprotein
Timepoint
before and after 8 weeks
Method of measurement
oxidised low density lipoprotein test on blood sample

9

Description
high sensitivity chronic phase reactive protein
Timepoint
before and after 8 weeks
Method of measurement
high sensitivity chronic phase reactive protein test on blood sample

10

Description
total antioxidant capacity
Timepoint
before and after 8 weeks
Method of measurement
total antioxidant capacity test on blood sample

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Consumption of 400 mg capsules of green coffee extract twice a day for half an hour before lunch or dinner, for 8 weeks
Category
Other

2

Description
Control group: Taking placebo capsules containing 500 mg of starch, 2 times a day, half an hour before lunch and dinner for 8 weeks
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Arvand petrochemical company
Full name of responsible person
Majid Mohammad shahi
Street address
Site 3, Special Economic Zone
City
Bandar emam khomeini
Province
Khouzestan
Postal code
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Phone
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Email
shsalamat@arvandpvc.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Ahmad Zare javid
Street address
Golestan, Jundishapur University of Medical Sciences, Faculty of Paramedicine
City
Ahwaz
Province
Khouzestan
Postal code
6356111111
Phone
+98 61 5212 6404
Email
ahmaddjavid@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor

organization/entity?
Yes
Title of funding source
Ahvaz University of Medical Sciences
Proportion provided by this source
20
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

2

Sponsor
Name of organization / entity
Arvand Petrochemical Company
Full name of responsible person
Naghi Ghasemian azizi
Street address
Special Economic Zone, site3
City
Bandar Imam Khomeini
Province
Khouzestan
Postal code
61563111111
Phone
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Email
shsalamat@arvandpvc.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arvand Petrochemical Company
Proportion provided by this source
80
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
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Majid Mohammad shahi
Position
Associate 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
arvand petrochemical company
Full name of responsible person
Shekoufeh Salamat
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Other areas of specialty/work
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Phone
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Fax
Email
shsalamat@arvandpvc.ir

Person responsible for updating data

Contact
Name of organization / entity
arvand petrochemical company
Full name of responsible person
Shekoufeh Salamat
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Nutrition
Street address
site3, special economic zone
City

Bandar emam khomeini
Province
Khouzestan
Postal code
6353131111
Phone
+98 61 5223 3609
Fax
Email
shsalamat@arvandpvc.ir

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
No more information
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be 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