

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 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 blind, 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**

Khuzestan

**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**

Khuzestan

##### **Postal code**

۶۳۵۳۱۳۱۱۱۱

##### **Phone**

+98 61 5212 6404

##### **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**

Khuzestan

##### **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**

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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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golestan Ave., Univesity Blvd

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**Phone**

+98 61 3373 8253

**Email**

shahi334@gmail.com

**Person responsible for scientific inquiries****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

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**City**

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**Province**

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**Phone**

+98 61 5223 3609

**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

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6353131111

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**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