Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Supplementation effect of green coffee bean extract on lipid profile, inflammatory and oxidative stress biomarkers, insulin resistance and liver enzymes in overweight and obese patients with nonalcoholic fatty liver disease(NAFLD).

Protocol summary

Summary

The purpose of this study is to assess the effect of green coffee bean extract on lipid profile, inflammatory and oxidative stress biomarkers, insulin resistance and liver enzymes in overweight and obese patients with nonalcoholic fatty liver disease (NAFLD). In this randomized, double blind, placebo controlled trial with parallel design,44 patients suffering from NAFLD will be selected among patients referring to Gastroenterology Clinic of Imam Khomeini Hospital in Ahvaz. Participants will be randomly assigned to intervention or control group (1:1 ratio) based on the blocked randomization method. The intervention and control groups respectively will be received green coffee bean extract capsule (1g per day) and Nokhodchi flour capsule (1g per day) as placebo for 8 weeks. Inclusion criteria include Patients aged between 20 to 70 years who will be diagnosed with NAFLD by ultrasonography scan and increased levels of liver enzymes; and have a Body Mass Index (BMI) grater than 24.9 and lower than 35. Exclusion criteria for the study will be alcohol consumption; pregnant and lactating women; any forms of hepatic or metabolic disease except NAFLD; taking hepatotoxic drugs; using nutrition supplements and have any history of gastric bypass or intestine surgery. At the beginning and end of the study different variables of the study include blood levels of lipid profile, inflammatory and oxidative stress biomarkers, insulin resistance and liver enzymes will be measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016030626941N1**

Registration date: **2016-04-19, 1395/01/31**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-04-19, 1395/01/31

Registrant information

Name

Hedayat allah Shahmohammadi

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 61 3373 8319

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2016-03-24, 1395/01/05

Expected recruitment end date

2016-04-18, 1395/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Supplementation effect of green coffee bean extract on

lipid profile, inflammatory and oxidative stress biomarkers, insulin resistance and liver enzymes in overweight and obese patients with nonalcoholic fatty liver disease(NAFLD).

Public title
Effect of green coffee bean extract supplementation on nonalcoholic fatty liver disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: Men or women aged between 20 to 70 years old who will be diagnosed with NAFLD by ultrasonography scan (with steatosis score equal or greater than 1) and increased levels of liver enzymes (serum levels of alanine aminotransferase and aspartate aminotransferase more than 40 U/L); and Body Mass Index (BMI) of them is grater than 24.9 and lower than 35. Exclusion criteria: Alcohol consumption; Pregnant and lactating women; Any known forms of hepatic or metabolic disease except NAFLD, such as hereditary hemochromatosis, Wilson's disease, cirosis, diabetes and other metabolic disease; Any history of gastric bypass or intestine surgery; Taking hepatotoxic drugs such as calcium channel blocker, methotrexate, amiodarone, chloroquine and anti inflammatory drugs; Using nutrition supplements; Hormone Therapy; and Patients with a history of hypothyroidism, Cushing's syndrome, renal failure, and kidney stones.
Age
From **20 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **44**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
participants will be randomly assigned to intervention or control group (1:1 ratio) based on the blocked randomization method

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Ahvaz Jundishapur University Of Medical Sciences
Street address
Golestan Ave., Ahvaz, Ahvaz Jundishapur University of Medical Sciences, Ethics Committee of Ahvaz Jundishapur University Of Medical Sciences
City
Ahvaz
Postal code
Approval date
2016-03-05, 1394/12/15
Ethics committee reference number
IR.AJUMS.REC. 1394.710

Health conditions studied

1

Description of health condition studied
Nonalcoholic Fatty Liver Disease
ICD-10 code
K76.0
ICD-10 code description
Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description
Liver steatosis index
Timepoint
Before and after intervention
Method of measurement
Sonography

2

Description
Insulin Resistance (IR)
Timepoint
Before and after intervention
Method of measurement
Based on HOMA IR equation

3

Description
Liver enzymes (ALT, AST, ALP)
Timepoint
Before and after intervention
Method of measurement
Microgram/ml - laboratory kit

4

Description
Tomor necrosis factor alpha (TNF alpha)
Timepoint

Before and after intervention

Method of measurement

ELISA

5

Description

Serum Total Anti Oxidant Capacity (TAOC)

Timepoint

Before and after intervention

Method of measurement

ELISA

6

Description

High sensitive C reactive protein

Timepoint

Before and after intervention

Method of measurement

ELISA

7

Description

Blood free fatty acids

Timepoint

Before and after intervention

Method of measurement

ELISA

8

Description

Lipid profile (TG, LDL, HDL, Total cholestrol)

Timepoint

Before and after intervention

Method of measurement

laboratory kit

9

Description

Fasting Blood Sugar (FBS)

Timepoint

Before and after intervention

Method of measurement

Colorimetric enzymatic method

10

Description

Insulin

Timepoint

Before and after intervention

Method of measurement

ELISA

Secondary outcomes

1

Description

Waist to hip ratio

Timepoint

Before and after intervention

Method of measurement

Non-stretchable tape without any pressure

2

Description

Body Mass Index (BMI)

Timepoint

Before and after intervention

Method of measurement

Weight (kilograms) divided by the square of height (meters)

3

Description

Sistolic and diastolic blood pressure

Timepoint

Before and after intervention

Method of measurement

By mercury sphygmomanometer

Intervention groups

1

Description

Intervention group: All patients will receive 1g green coffee bean extract capsules once daily for 8 weeks.

Category

Treatment - Drugs

2

Description

Control group: All patients will receive 1g placebo capsules (Nokhodchi flour) once daily for 8 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Gastroenterology Outpatient Clinic affiliated to Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Eskandar Hajiani

Street address

Azadegan Ave., Ahvaz, Department of Gasteroenterology, Imam Khomeini Hospital

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for research of Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person
Dr Nader Saki, Deputy of research development

Street address
Golestan Ave., Ahvaz, Vice Chancellor for research of Ahvaz Jundishapur University of Medical Sciences

City
Ahvaz

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 Ahvaz Jundishapur University of Medical Sciences

Proportion provided by this source
100

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
Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person
Hedayat allah shahmohammadi

Position
MSc student of Nutrition

Other areas of specialty/work

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Other areas of specialty/work

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shahmohammadi.h@ajums.ac.ir; hedaiat.sh68@gmail.com

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