Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Nov 2026

Effect of green coffee extract supplementation on metabolic status, serum leptin level and anthropometric measurements in patients with non-alcoholic fatty liver disease

Protocol summary

Study aim
Investigation of the effect of green coffee extract supplementation on metabolic and oxidative status, serum leptin and adiponectin levels and anthropometric measurements in patients with non-alcoholic fatty liver disease (NAFLD).

Design
A randomized, double-blind, placebo-controlled trial

Settings and conduct
48 patients with NAFLD will be randomly divided into two intervention groups:1. green coffee extract recipient group (one 200 mg capsule after breakfast and one after lunch) 2. placebo group (a placebo capsule containing 200 mg starch after breakfast and one after lunch). Subjects will be recruited from 22 Bahman poly-clinic in Neyshabur, Iran.

Participants/Inclusion and exclusion criteria
48 patients with NAFLD will be randomly divided into two intervention groups:1. green coffee extract recipient group (one 200 mg capsule after breakfast and one after lunch) 2. placebo group (a placebo capsule containing 200 mg starch after breakfast and one after lunch). The main criteria for inclusion are observing hepatic steatosis on ultrasound, age range 20-50 years for women and 20-60 years for men; body mass index (BMI) greater than 25 and less than 35 kilograms per square meter. The main exclusion criteria are alcohol intake; pregnancy, lactation, and menopause; liver transplantation; cancers; Inherited disorders affecting the liver status; consumption of hepatotoxic drugs, anticoagulants, and vitamin supplements.

Intervention groups
Group 1: green coffee extract recipient Group 2: Placebo recipient

Main outcome variables
Metabolic and oxidative status, serum leptin and adiponectin levels and anthropometric measurements

General information

Reason for update
Adding new factors of supplementary research in this study

Acronym

IRCT registration information
IRCT registration number: **IRCT201602113664N17**
Registration date: **2016-04-08, 1395/01/20**
Registration timing: **registered_while_recruiting**

Last update: **2019-12-12, 1398/09/21**
Update count: **1**

Registration date
2016-04-08, 1395/01/20

Registrant information

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Maryam Rafraf

Name of organization / entity
Tabriz University Of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
Student research center of Tabriz University of Medical Sciences

Expected recruitment start date
2016-04-03, 1395/01/15

Expected recruitment end date
2016-09-05, 1395/06/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of green coffee extract supplementation on metabolic status, serum leptin level and anthropometric measurements in patients with non-alcoholic fatty liver disease

Public title

The effect of green coffee extract in the treatment of non-alcoholic fatty liver disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Nonalcoholic fatty liver (observation of liver steatosis on Sonographic image) The age range of 20-50 years in women and 20-60 years in men Body mass index greater than 25 and less than 35 kilograms per Square meters

Exclusion criteria:

Alcohol intake Gestation, Lactation, and Menopause Following a weight reducing diet Professional athletes History or current diagnosis of anemia, cardiovascular disease; gastrointestinal disease, diabetes, pulmonary disease, renal disease, acute or chronic liver disorders (Hepatitis A, B, ...), biliary impairments, biliary or kidney stones; autoimmune disease, cancers, Inherited disorders affecting the liver, and other diseases Use of medications such as hepatotoxic drugs, anticoagulant drugs, hormonal drugs (e.g., oral contraceptives and/or estrogen), and consuming dietary supplements such as vitamin A, E, C, and omega-3 three months prior to the study and/or during the study period.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

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

Sample size

Target sample size: **48**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization was carried out using a block randomization procedure of size 4 and was stratified by age, sex, and BMI. Random allocation software (RAS) was used for generating a random sequence.

Blinding (investigator's opinion)

Double blinded

Blinding description

An independent person not involved in the study process prepared both green coffee extract and placebo bottles and labeled them as A or B. All of the supplement packs were identically provided. The patients and researchers were all blinded to the treatment assignment until the statistical analyses were completed.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Tabriz University of Medical Science

Street address

Tabriz University of Medical Sciences, Golgasht Ave, Tabriz, East Azerbaijan

City

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East Azarbaijan

Postal code

5165665931

Approval date

2016-02-10, 1394/11/21

Ethics committee reference number

TBZMED.REC.1394.1031

2

Ethics committee

Name of ethics committee

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Golgasht Ave, Tabriz University of Medical Sciences,

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Approval date

2019-11-24, 1398/09/03

Ethics committee reference number

IR.TBZMED.REC.1398.918

Health conditions studied

1

Description of health condition studied
Non-alcoholic fatty liver
ICD-10 code
K 76
ICD-10 code description
Fatty liver

Primary outcomes

1

Description
Fasting Blood sugar
Timepoint
Baseline and after the intervention
Method of measurement
Spectrophotometery

2

Description
Liver Enzymes (Alanine aminotransferase, Aspartate aminotransferase)
Timepoint
Baseline and after the intervention
Method of measurement
Spectrophotometery

3

Description
Serum leptin level
Timepoint
Baseline and after the intervention
Method of measurement
ELISA

4

Description
Liver Echogenicity
Timepoint
Baseline and after the intervention
Method of measurement
Liver sonography

5

Description
Body Mass Index
Timepoint
Baseline and after the intervention
Method of measurement
(weight/(Height)2),

6

Description
Insulin
Timepoint
Baseline and after the intervention
Method of measurement
ELISA

7

Description
Waist Circumference
Timepoint
Baseline and after the intervention
Method of measurement
Cm

8

Description
Serum adiponectin level
Timepoint
Baseline and after the intervention
Method of measurement
ELISA

9

Description
Oxidative status (TAC, MDA)
Timepoint
Baseline and after the intervention
Method of measurement
Biochemical

Secondary outcomes

1

Description
Systolic and diastolic blood pressure
Timepoint
Beginning and eighth week of the study
Method of measurement
By Mercury Barometer

Intervention groups

1

Description
Intervention Group: Intake of Green coffee extract 200 mg capsules two times a day, Prepared by Bonian Salamat Kasra company, for 8 weeks.
Category
Treatment - Drugs

2

Description
Placebo groups: Intake a Placebo capsule containing 200 mg of starch, which is similar to green coffee extract supplement in terms of dosage, color and size, twice a day for 8 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
22 Bahman hospital
Full name of responsible person
Samaneh Hosseinabadi
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Sponsors / Funding sources

1

Sponsor

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Tabriz 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
Nutrition and Food Sciences Faculty, Tabriz University of Medical Sciences
Full name of responsible person
Samaneh Hosseinabadi
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable