

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 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

Name

Maryam Rafraf

Name of organization / entity

Tabriz University Of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

rafrafm@tbzmed.ac.ir

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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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

Ethics Committee of Tabriz University of Medical Science

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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

Spectrophotometry

2

Description

Liver Enzymes (Alanine aminotransferase, Aspartate aminotransferase)

Timepoint

Baseline and after the intervention

Method of measurement

Spectrophotometry

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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Imam Khomeini Ave, Iran Sq, Neyshabor

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Position

MSc Student of Nutrition Sciences

Latest degree

Bachelor

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

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

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Latest degree

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Other areas of specialty/work

nutrition

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Web page address**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