

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The Effect of Beetroot Extract supplementation on metabolic, hepatic, and inflammation parameters in patients with metabolic-dysfunction associated Steatotic liver disease.

Protocol summary

Study aim

The Effect of Beetroot Extract supplementation on metabolic, hepatic, and inflammation parameters in patients with metabolic-dysfunction associated Steatotic liver disease.

Design

A phase 3 randomized, double-blind, controlled, parallel-group clinical trial on 50 patients.

Settings and conduct

This study is conducted at Behbood clinic. Patients with fatty liver disease who met the eligibility criteria were enrolled after providing written informed consent. At baseline, demographic data, weight, height, fasting blood samples, and 24-hour dietary recall were collected. Participants were categorized by BMI and randomly assigned, using block randomization, to receive either beetroot extract supplement (1 g daily for 12 weeks) or placebo. Both groups followed a hypocaloric diet. For blinding, the supplement and placebo capsules were coded as A and B, ensuring that neither patients nor investigators were aware of group assignments.

Participants/Inclusion and exclusion criteria

Entry criteria: 1.Age 18–65 years 2.Steatosis degree above 263 on FibroScan 3.BMI > 25 Exclusion criteria: 1.Unwillingness to continue the trial or non-adherence to the intervention 2.Pregnancy or lactation 3.Alcohol consumption 4.Presence of other liver diseases 5.Presence of cirrhosis or hepatic cancer 6.Use of corticosteroid medications 7.Use of hepatotoxic drugs 8.Use of liver-affecting supplements within the past 6 months 9.Changes in medication use 10.Use of weight-loss medications or supplements 11.Following any type of weight-loss diet within the past 3 months

Intervention groups

Beetroot extract (1000 mGr/daily)

Main outcome variables

Weight, waist circumference, hip circumference, waist-

to-hip ratio (WHR), fasting blood glucose (FBG), liver enzymes, C-reactive protein (CRP), lipid profile, hepatic steatosis and fibrosis, insulin.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100524004010N42**

Registration date: **2025-10-20, 1404/07/28**

Registration timing: **prospective**

Last update: **2025-10-20, 1404/07/28**

Update count: **0**

Registration date

2025-10-20, 1404/07/28

Registrant information

Name

Azita Hekmatdoost

Name of organization / entity

Shahid Beheshti University of Medical Sciences,
National Institute of Nutrition Research

Country

Iran (Islamic Republic of)

Phone

+98 21 2293 0824

Email address

hekmat@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-10-23, 1404/08/01

Expected recruitment end date

2026-05-22, 1405/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Beetroot Extract supplementation on metabolic, hepatic, and inflammation parameters in patients with metabolic-dysfunction associated Steatotic liver disease.

Public title

The Effect of Beetroot Extract supplementation on metabolic, hepatic, and inflammation parameters in patients with metabolic-dysfunction associated Steatotic liver disease.

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 18 and 65 years old Diagnosis of metabolic dysfunction-associated steatotic liver disease (MASLD) confirmed by a gastroenterology subspecialist Liver steatosis score >263 on FibroScan Body mass index (BMI) >25

Exclusion criteria:

Lack of willingness to continue participation or non-adherence to the intervention Pregnancy or lactation Alcohol consumption Presence of other liver diseases Presence of cirrhosis or hepatocellular carcinoma Use of corticosteroid medications such as prednisolone, hydrocortisone, or betamethasone Use of hepatotoxic drugs such as tamoxifen, phenytoin, amoxifen, or lithium Use of liver-affecting supplements (e.g., fiber, omega-3, antioxidants) during the past 6 months Changes in medications (lipid-lowering agents, antidiabetic drugs) during study participation Use of weight-loss drugs or supplements Following any type of weight-loss diet within the past 3 months Weight reduction greater than 10% in the last 6 months (prior to enrollment)

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were categorized into three groups based on

their Body Mass Index (BMI): Group 1 with BMI between 25 and 30 (<30), Group 2 with BMI between 30 and 35 (<35), and Group 3 with BMI between 35 and 40. Using a randomized block design, participants in each BMI category were randomly assigned to either the beetroot extract supplementation group or the placebo group. To ensure balanced allocation, a stratified blocked randomization method was applied, with separate randomization conducted within each BMI stratum. The block size was set at four, including two allocations to Group A (beetroot extract) and two allocations to Group B (placebo). Six possible permutations of allocation sequences were used: AABB, ABAB, BBAA, BABA, ABBA, and BAAB.

Blinding (investigator's opinion)

Double blinded

Blinding description

For blinding purposes, an independent individual outside the research team is responsible for preparing the supplement and placebo, which are randomly assigned and labeled as groups A and B. Neither participants, investigators, nor outcome assessors are aware of the allocation (supplement or placebo) until the completion of the study and data analysis. The group codes will be disclosed only after data analyses have been completed, at the stage of manuscript preparation.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

National nutrition and food technology research institute

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No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town,

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Tehran

Province

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Postal code

1981619573

Approval date

2025-08-05, 1404/05/14

Ethics committee reference number

IR.SBMU.NNFTRI.REC.1404.029

Health conditions studied

1

Description of health condition studied

Fatty liver

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description

Hepatic steatosis

Timepoint

Before intervention and after 12 weeks

Method of measurement

Fibroscan

Secondary outcomes

1

Description

Blood glucose profile

Timepoint

At the beginning and end of the study (week 12)

Method of measurement

Blood test

2

Description

Blood lipid profile

Timepoint

At the beginning and end of the study (week 12)

Method of measurement

Blood test

3

Description

Liver enzymes

Timepoint

At the beginning and end of the study (week 12)

Method of measurement

Blood test

4

Description

C-reactive Protein

Timepoint

At the beginning and end of the study (week 12)

Method of measurement

Blood test

Intervention groups

1

Description

ntervention group: Participants in this group received beetroot extract supplementation (1 g per day equivalent to two 500mgr tablets) in combination with a calorie-restricted weight loss diet.

Category

Treatment - Other

2

Description

Control group: Participants in this group received a placebo (1 g per day, equivalent to two placebo capsules identical in appearance to the supplement) in combination with a calorie-restricted weight loss diet.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Behbood clinic

Full name of responsible person

Mohammad Hossein Ebrahimizadeh

Street address

Mofateh street, ave 14

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Postal code

1587844611

Phone

+98 21 8817 1901

Email

info@clinicbehbood.com

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Naser Kalantari

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No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town,

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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

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

1

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

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Azita Hekmatdoost

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available