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, andinflammation parameters in patients with metabolic-dysfunction associatedSteatotic 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
Street address
No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town,
City
Tehran
Province
Tehran
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
City
Tehran
Province
Tehran
Postal code
1587844611
Phone
+98 21 8817 1901
Email
info@clinicbehhbood.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
Street address
No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town,
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Phone

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Email

info@nnft.ac.ir

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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Position

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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

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