Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jul 2026

Combined effect of Low Carbohydrate Diet (LCD) with Time-restricted feeding (TRF) on anthropometric indicators, liver parameters, metabolic indices and inflammation in patients with non-alcoholic fatty liver

Protocol summary

Study aim

Determine the effect of combined low-carbohydrate diet with time-limited feeding method on anthropometric indicators, liver parameters, metabolic factors and Inflammation in patients with non-alcoholic fatty liver disease

Design

A clinical trial with a control group, with parallel groups, without blinding and randomized with a sample of 50 people. A table of random numbers was used for randomization.

Settings and conduct

NAFLD Patients referred to Tehran's GI clinics with the desired criteria and personal satisfaction were selected and fibroscanned, and in case of steatosis grade 2 or higher based on CAP score>263, after 12-14 hours of fasting, 5 cc of blood is taken for biochemical evaluation. At the beginning and the end, weight, height, BMI, general profile and physical activity questionnaire are completed and the 24-hour-food recall is filled for three days at the beginning, week 6 and 12. 24-hour food recall analysis is done with Nutritionist-IV and all patients are given dietary-physical activity advice. For 12 weeks, the intervention group was prescribed a LCD+TRF, but control group only received dietary recommendations. At the end, fibroscan and blood test are repeated and weight and BMI are recalculated.

Participants/Inclusion and exclusion criteria

Non-alcoholic fatty-liver patients

Intervention groups

The intervention group is prescribed a low-carbohydrate-diet and time-limited-feeding for 12 weeks and patients in the control group only receive dietary recommendations.

Main outcome variables

Determining and comparing weight, BMI,waist and hip circumference, physical activity, total energy, protein, carbohydrate, fiber, total-fat, SFA, MUFA, PUFA, cholesterol, vitamin-E, vitamin-C, zinc, selenium in the diet, ALT, AST, degree of steatosis and liver fibrosis, glucose homeostasis indices, lipid profile and hs-CRP at the beginning and end of the two groups and in each group.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100524004010N40**
Registration date: **2025-03-15, 1403/12/25**
Registration timing: **prospective**

Last update: **2025-03-15, 1403/12/25**
Update count: **0**

Registration date

2025-03-15, 1403/12/25

Registrant information

Name

Azita Hekmatdoost

Name of organization / entity

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

Country

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-03-30, 1404/01/10

Expected recruitment end date

2025-10-02, 1404/07/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Combined effect of Low Carbohydrate Diet (LCD) with Time-restricted feeding (TRF) on anthropometric indicators, liver parameters, metabolic indices and inflammation in patients with non-alcoholic fatty liver

Public title

Combined effect of Low Carbohydrate Diet (LCD) with Time-restricted feeding (TRF) on anthropometric indicators, liver parameters, metabolic indices and inflammation in patients with non-alcoholic fatty liver

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 and above Hepatic steatosis grade 2 or higher based on Fibro scan results (CAP score >263) Not having a history of alcohol consumption or consuming less than 10 mg of alcohol per day in women and less than 20 mg per day in men. No insulin treatment Having the desire to participate in the study and the ability to complete the study steps Absence of other chronic and acute liver diseases and disorders (hepatitis B, C, etc.), biliary disease, kidney diseases, endocrine disorders, known autoimmune diseases, cancer, and hereditary disorders affecting the liver (hemochromatosis, Wilson's, etc.) Absence of cardiovascular disease, chronic inflammatory disease and disorders of the digestive system affecting absorption (celiac disease, etc.) Absence of pregnancy or breastfeeding in women Not receiving corticosteroid drugs such as Prednisolone, Hydrocortisone and Betamethasone Not taking hepatotoxic drugs such as Tamoxifen, Phenytoin and Lithium Not taking fiber, omega-3 and antioxidant supplements during the last 6 months Not taking drugs or weight loss supplements No history of weight loss surgery or weight loss program in the last 3 months Absence of liver cirrhosis or Fibro score higher than 12

Exclusion criteria:

Changes in medications (blood lipid-lowering drugs, blood sugar control drugs) during the study period Weight loss of more than 10% during the last 6 months Weight loss of more than 10% during the study period Unwillingness to participate in the study or non-adherence to the prescribed regimens

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

The table of random numbers is used to classify people into intervention and control groups.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of National Nutrition and Food Technology Research Institute (NNFTRI)

Street address

No. 7, Shahid Hafezi Ave., Farahzadi Blvd., Western Qods Town

City

Tehran

Province

Tehran

Postal code

1981619573

Approval date

2025-01-22, 1403/11/03

Ethics committee reference number

IR.SBMU.NNFTRI.REC.1403.076

Health conditions studied

1

Description of health condition studied

Fatty liver disease

ICD-10 code

K75.81

ICD-10 code description

Nonalcoholic steatohepatitis (NASH)

Primary outcomes

1

Description

CAP (Controlled Attenuation Parameter) Score

Timepoint

At the beginning of the study and week 12

Method of measurement
The result of the fibro scan

Secondary outcomes

1

Description
The degree of hepatic steatosis
Timepoint
The beginning of the study and week 12
Method of measurement
Based on the results of the fibro scan

2

Description
The degree of liver fibrosis
Timepoint
The beginning of the study and week 12
Method of measurement
Based on the results of the fibro scan

3

Description
Alanine transaminase
Timepoint
The beginning of the study and week 12
Method of measurement
Enzymatic method using kit

4

Description
Aspartate aminotransferase
Timepoint
The beginning of the study and week 12
Method of measurement
Enzymatic method using kit

5

Description
Serum triglycerides
Timepoint
The beginning of the study and week 12
Method of measurement
Enzymatic method using kit

6

Description
Total serum cholesterol
Timepoint
The beginning of the study and week 12
Method of measurement
Enzymatic method using kit

7

Description
Serum Low-density lipoprotein (LDL)
Timepoint
The beginning of the study and week 12
Method of measurement
Enzymatic method using kit

8

Description
Serum High-density lipoprotein (HDL)
Timepoint
The beginning of the study and week 12
Method of measurement
Enzymatic method using kit

9

Description
Serum High-sensitivity C-reactive protein (hs-CRP)
Timepoint
The beginning of the study and week 12
Method of measurement
ELISA method

10

Description
Serum glucose
Timepoint
The beginning of the study and week 12
Method of measurement
Enzymatic method using kit

11

Description
Serum insulin
Timepoint
The beginning of the study and week 12
Method of measurement
Radioimmunoassay

12

Description
Homeostatic Model Assessment for Insulin Resistance (HOMA-IR)
Timepoint
The beginning of the study and week 12
Method of measurement
Calculation

13

Description
Quantitative Insulin Sensitivity Check Index (QUICKI)
Timepoint
The beginning of the study and week 12
Method of measurement
Calculation

14

Description
Type of diet received

Timepoint
The beginning of the study
Method of measurement
Data collection form

15

Description
Weight
Timepoint
The beginning of the study and week 12
Method of measurement
Weight scale

16

Description
Height
Timepoint
The beginning of the study
Method of measurement
Stadiometer

17

Description
Body mass index (BMI)
Timepoint
The beginning of the study and week 12
Method of measurement
Calculation

18

Description
Sex
Timepoint
The beginning of the study
Method of measurement
Observation

19

Description
Age
Timepoint
The beginning of the study
Method of measurement
Question

20

Description
Smoking
Timepoint
The beginning of the study
Method of measurement
Question

21

Description
Total energy intake
Timepoint
The beginning of the study, week 6 and 12
Method of measurement
24-hour food recall questionnaire (2 working days and 1 day off)

22

Description
Carbohydrate intake
Timepoint
The beginning of the study, week 6 and 12
Method of measurement
24-hour food recall questionnaire (2 working days and 1 day off)

23

Description
Protein intake
Timepoint
The beginning of the study, week 6 and 12
Method of measurement
24-hour food recall questionnaire (2 working days and 1 day off)

24

Description
Total fat intake
Timepoint
The beginning of the study, week 6 and 12
Method of measurement
24-hour food recall questionnaire (2 working days and 1 day off)

25

Description
Cholesterol intake
Timepoint
The beginning of the study, week 6 and 12
Method of measurement
24-hour food recall questionnaire (2 working days and 1 day off)

26

Description
Saturated fatty acids (SFA) intake
Timepoint
The beginning of the study, week 6 and 12
Method of measurement
24-hour food recall questionnaire (2 working days and 1 day off)

27

Description
Monounsaturated fatty acids (MUFA) intake
Timepoint
The beginning of the study, week 6 and 12
Method of measurement
24-hour food recall questionnaire (2 working days and 1

day off)

28

Description
Polyunsaturated fatty acids (PUFA) - omega 3 intake
Timepoint
The beginning of the study, week 6 and 12
Method of measurement
24-hour food recall questionnaire (2 working days and 1 day off)

29

Description
Polyunsaturated fatty acids (PUFA) - omega 6 intake
Timepoint
The beginning of the study, week 6 and 12
Method of measurement
24-hour food recall questionnaire (2 working days and 1 day off)

30

Description
Fiber intake
Timepoint
The beginning of the study, week 6 and 12
Method of measurement
24-hour food recall questionnaire (2 working days and 1 day off)

31

Description
Vitamin E intake
Timepoint
The beginning of the study, week 6 and 12
Method of measurement
24-hour food recall questionnaire (2 working days and 1 day off)

32

Description
Vitamin C intake
Timepoint
The beginning of the study, week 6 and 12
Method of measurement
24-hour food recall questionnaire (2 working days and 1 day off)

33

Description
Zinc intake
Timepoint
The beginning of the study, week 6 and 12
Method of measurement
24-hour food recall questionnaire (2 working days and 1 day off)

34

Description
Selenium intake
Timepoint
The beginning of the study, week 6 and 12
Method of measurement
24-hour food recall questionnaire (2 working days and 1 day off)

35

Description
Physical activity
Timepoint
The beginning of the study and week 12
Method of measurement
Metabolic equivalent of task (MET) questionnaire

36

Description
Waist circumference
Timepoint
The beginning of the study and week 12
Method of measurement
Tape measure

37

Description
Hip circumference
Timepoint
The beginning of the study and week 12
Method of measurement
Tape measure

Intervention groups

1

Description
Intervention group: The intervention group was simultaneously administered a low-carbohydrate diet and time-restricted feeding (16 hours of fasting and 8 hours for food consumption) for 12 weeks. The diet is tailored to each individual's calorie needs. Individuals are provided with recommendations for general health, liver health, and physical activity.
Category
Treatment - Other

2

Description
Control group: Patients in the control group only receive dietary recommendations related to general health and liver health and physical activity.
Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Behbood gastroenterology specialist clinic

Full name of responsible person
Azita Hekmatdoost

Street address
No. 2, Behbood gastroenterology specialist clinic, Northern Mofateh Ave., Shahid Beheshti street

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1587844611

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Afshin Zarghi

Street address
No. 2, Arabi Ave., Daneshjoo Blvd., Velenjak

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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
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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Azita Hehmatdoost

Position
Professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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Position
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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
Yes - There is 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
Title and more details about the data/document
N/A
When the data will become available and for how long
N/A
To whom data/document is available
N/A
Under which criteria data/document could be used
N/A
From where data/document is obtainable
N/A
What processes are involved for a request to access data/document
N/A
Comments