

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

The effect of moderate carbohydrate restriction diet on liver enzymes, steatosis and fibrosis in normal weight individuals with non-alcoholic fatty liver disease: a parallel randomized controlled clinical trials

Protocol summary

Study aim

Determining the effect of moderate carbohydrate restriction diet on liver enzymes, steatosis and fibrosis in normal weight individuals with non-alcoholic fatty liver disease

Design

A clinical trial with a control group, parallel group, randomized groups, on 52 patients. lottery container was used for randomization.

Settings and conduct

A controlled clinical trial will be performed at the Gastroenterology Clinic. Before the intervention anthropometric and biochemical assessment, steatosis and liver fibrosis assessment by Fibro-scan will be done. Individuals will be randomly divided into intervention and control groups. The subjects in the intervention group will be received a moderate carbohydrate-restricted diet, which included 40-45% of energy from carbohydrates, 35-40% of energy from fat, and the rest of energy from a source of protein for 12 weeks. The control group will be received an isocaloric diet for 12 weeks. The diet will be included 50-55% of energy from carbohydrates, 25-30% from fat, and the rest of energy from a source of protein.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1.Body mass index between 18.5-25 kg/m², 2. Aged 18-65 years, 3.Patients with non-alcoholic fatty liver disease. Non-inclusion criteria: 1.Consuming alcohol, 2.Pregnancy and breastfeeding 3. Suffering from other liver diseases, 4. Drug and tobacco use, 5. Consuming corticosteroids during the last three months, 6. Follow a weight loss diet during the last three months.

Intervention groups

Intervention group: intake of moderate carbohydrate restriction diet Control group: intake of isocaloric diet

Main outcome variables

Steatosis and liver enzymes including ALT, AST and GGT.

General information

Reason for update

According to the formula and considering the possible drop-out, we will be need 52 participants and 68 participants have been registered incorrectly. In the exclusion criteria section, according to the covid-19 pandemic and the individual's desire to use multivitamins to maintain and improve the immune system, we will include individuals who consume multivitamins and minerals. In the primary and secondary outcomes section, considering that the duration of the intervention to investigate liver fibrosis is short, we will consider liver fibrosis as a secondary outcome.

Acronym

IRCT registration information

IRCT registration number: **IRCT20210119050086N1**
Registration date: **2021-02-20, 1399/12/02**
Registration timing: **prospective**

Last update: **2022-08-28, 1401/06/06**

Update count: **2**

Registration date

2021-02-20, 1399/12/02

Registrant information

Name

Fatemeh Dashti

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8895 5975

Email address

fatemehda1996@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-22, 1400/09/01

Expected recruitment end date

2022-05-22, 1401/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of moderate carbohydrate restriction diet on liver enzymes, steatosis and fibrosis in normal weight individuals with non-alcoholic fatty liver disease: a parallel randomized controlled clinical trials

Public title

Effect of moderate restriction diet in treatment of non-alcoholic fatty liver disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Body mass index 18.5-25 kg/m² Age range 18-65 years Patients with non-alcoholic fatty liver disease

Exclusion criteria:

Alcohol consumption Pregnancy or breastfeeding Suffering from other liver diseases Consuming corticosteroids during the last three months Drugs or tobacco use Follow a weight loss diet during the last three months

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

Individuals will be classified based on age, gender (male/female) and BMI (± 2) into different blocks. To do randomization, an identification code will be given to each participant, and then the codes of each two participants with the same age, gender and BMI will be poured into the lottery container. Random allocation will be done by a person who is unaware of the study. The first code will be assigned to the intervention group, the second code to the control group and so other participants will be randomly assigned to the two 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 Tehran University of Medical Sciences

Street address

Office of the Vice Chancellor for Research, First Floor, Building No. 1, School of Medicine, North Door of the University, Poursina St., Ghods St., Enghelab St.

City

Tehran

Province

Tehran

Postal code

1411713114

Approval date

2021-01-10, 1399/10/21

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1399.964

Health conditions studied

1

Description of health condition studied

Non-alcoholic fatty liver disease

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description

Steatosis

Timepoint

Beginning the intervention and 12 weeks later at the end of the intervention

Method of measurement

Fibro-scan

2

Description

Liver enzyme (ALT, AST and GGT)

Timepoint

Beginning the intervention and 12 weeks later at the end of the intervention

Method of measurement

Blood sample

Secondary outcomes

1

Description

Lipid profile (TG, Total cholesterol, LDL-c and LDH-c)

Timepoint

Beginning the intervention and 12 weeks later at the end of the intervention

Method of measurement

Blood sample

2

Description

Glycemic index (FBS, FBI, HOMA-IR and QUICKI)

Timepoint

Beginning the intervention and 12 weeks later at the end of the intervention

Method of measurement

Blood sample

3

Description

Weight

Timepoint

Beginning the intervention and 12 weeks later at the end of the intervention

Method of measurement

Scales

4

Description

Waist circumference

Timepoint

Beginning the intervention and 12 weeks later at the end of the intervention

Method of measurement

Tape meter

5

Description

Body mass index (BMI)

Timepoint

Beginning the intervention and 12 weeks later at the end of the intervention

Method of measurement

Formula (weight (kilograms) divided by the squared height (meters))

6

Description

Fibrosis

Timepoint

Beginning the intervention and 12 weeks later at the end of the intervention

Method of measurement

Fibro-scan

Intervention groups

1

Description

Intervention group: Intake of moderate carbohydrate restriction diet, which included 40-45% of energy from carbohydrates, 35-40% of energy from fat, and the rest of energy from a source of protein.

Category

Treatment - Other

2

Description

Control group: Intake of isocaloric diet, which included 50-55% of energy from carbohydrates, 25-30% from fat, and the rest of energy from a source of protein.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr. Seyyed Moayed Alaviyan's clinic

Full name of responsible person

Fatemeh Dashti

Street address

No. 178, Corner of Shadab Crossroads, Above Taleghani, Sepahbod Gharani St., Ferdowsi Square

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alavian@thc.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Sahraeiyan

Street address

Vice Chancellor for Research and Technology, sixth floor, Central University Organization, corner of Ghods Street, Keshavarz Blvd.

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1417935840
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vcr@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran University of Medical Sciences
Proportion provided by this source
50
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
Tehran University of Medical Sciences
Full name of responsible person
Fatemeh Dashti
Position
Master student
Latest degree
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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