Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Jun 2026

The effect of moderate carbohyderate 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 carbohyderate 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
City
Tehran
Province
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Postal code
1417935840
Phone
+98 21 8890 7154
Email
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.
City
Tehran
Province

Tehran
Postal code
1417935840
Phone
+98 21 8163 3685
Email
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
Bachelor
Other areas of specialty/work
Nutrition
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No. 44, Hojjatdoost Alley, Naderi St., Keshavarz Boulevard
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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