Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Oct 2026

Comparison of the effect of a low-carbohydrate diet with restricted calories and a standard diet with restricted calories on the levels of liver enzymes, insulin resistance and body composition in obese or overweight children and adolescents with non-alcoholic fatty liver disease.

Protocol summary

Study aim

Determining the effect of a low-carbohydrate, calorie-restricted diet and a standard calorie-restricted diet on liver enzyme levels, insulin resistance, and body composition (including height, weight, body fat mass, body fat-free mass, and body water) in obese or overweight children and adolescents suffering from non-alcoholic fatty liver disease

Design

A double-arm, randomized clinical trial, with sample size of 60 people (30 people in each group)

Settings and conduct

Participants are selected from the number of people who refer to Tehran Children's Medical Center Hospital. If they are eligible, they will enter the study. In the case of blinding, the anthropometric evaluations and the measurement of biochemical factors in the blood samples of the participants will be done by persons who are not aware of the group of each participant.

Participants/Inclusion and exclusion criteria

Eligible participants in this study are children and adolescents aged 5 to 18 years with NAFLD and obesity or overweight. ⋆ Age 5 to 18 years ⋆ Obesity or overweight ⋆ NAFLD based on serum ALT levels Non-entry criteria: ⋆ suffering from other liver diseases ⋆ Suffering from autoimmune diseases ⋆ suffering from hereditary metabolic diseases ⋆ History of receiving intravenous nutrition ⋆ History of using steatogenic drugs ⋆ Alcohol consumption ⋆ Pregnancy

Intervention groups

Intervention group: the group receiving a low-carbohydrate diet with limited calories Control group: the group receiving the standard calorie-restricted diet

Main outcome variables

Liver enzyme levels (ALT and AST); body composition (including height, weight, body fat mass, body fat-free mass and body water); lipid profile (TG, TC, LDL, HDL); insulin resistance (by HOMA-IR index); Fasting plasma glucose

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151128025267N8**
Registration date: **2025-02-16, 1403/11/28**
Registration timing: **registered_while_recruiting**

Last update: **2025-02-16, 1403/11/28**
Update count: **0**

Registration date

2025-02-16, 1403/11/28

Registrant information

Name
Maryam Mahmoudi
Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-11-21, 1403/09/01

Expected recruitment end date
2025-03-20, 1403/12/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of a low-carbohydrate diet with restricted calories and a standard diet with restricted calories on the levels of liver enzymes, insulin resistance and body composition in obese or overweight children and adolescents with non-alcoholic fatty liver disease.

Public title
Comparison of two different types of diet on the levels of factors related to non-alcoholic fatty liver disease in children and adolescents
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 5 to 18 years Obesity or overweight NAFLD based on serum ALT levels
Exclusion criteria:
Suffering from other liver diseases Suffering from autoimmune diseases Suffering from hereditary metabolic diseases History of receiving parental nutrition History of taking steatogenic drugs alcohol consumption pregnancy
Age
From **5 years** old to **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
The participants were randomly divided into two groups: a standard calorie-restricted diet and a calorie-restricted low-carbohydrate diet. A block randomization scheme is used for randomization. The randomization process as mentioned above was done online and by the sealedenvelope website at the address (https://www.sealedenvelope.com/simple-randomiser/v1/lists) and then the output of its production sequence was received in the form of an Excel file. The closed envelope method will be used to perform randomization; For this purpose, 60 envelopes are numbered from 1 to 60 and then according to the random sequence, they are written on papers and sealed inside the envelope according to the received regime. The participants were given an envelope by the relevant nutritionist in the order that they enter the study, and based on the diet in the envelope, they are divided into one of two study groups, i.e., a low-carb diet with limited calories or a standard diet with limited calories.
Blinding (investigator's opinion)
Single blinded
Blinding description
Anthropometric evaluations as well as measurement of biochemical factors in the participants' blood samples will be performed by persons who are not aware of each participant's group, and so-called blinding is done in the case of biochemical evaluations and anthropometry.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
hildren’s Medical Center-Tehran University of Medical Sciences
Street address
Secretariat of Ethics Committee in Biomedical Research, University of Tehran, Keshavarz Blvd., Intersection of Quds St., Central Building of Tehran University of Medical Sciences, 6th Floor, Room 604
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Tehran
Province
Tehran
Postal code
1419733151
Approval date
2024-05-14, 1403/02/25
Ethics committee reference number
IR.TUMS.CHMC.REC.1403.051

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
Alanine amino teransferase

Timepoint
One week before the beginning of the study and immediately after the end of the study (the intervention period is 12 weeks)
Method of measurement
Blood test and measurement of its values in serum

2

Description
Aspartate amino teransferase
Timepoint
One week before the beginning of the study and immediately after the end of the study (the intervention period is 12 weeks)
Method of measurement
Blood test and measurement of its values in serum

Secondary outcomes

1

Description
Insulin resistance by HOMA-IR index
Timepoint
before the beginning of the study and immediately after the end of the study (the intervention period is 12 weeks)
Method of measurement
First, measuring fasting glucose and insulin in the serum and then calculating by the formula (Insulin (mU/L) × Glucose (mg/dL)) / 405

2

Description
Serum insulin
Timepoint
before the beginning of the study and immediately after the end of the study (the intervention period is 12 weeks)
Method of measurement
Enzymatic spectrophotometer method

3

Description
Serum glucose
Timepoint
before the beginning of the study and immediately after the end of the study (the intervention period is 12 weeks)
Method of measurement
The glucose oxidase-peroxidase coupled method (GOD-POD)

4

Description
Serum triglyceride
Timepoint
before the beginning of the study and immediately after the end of the study (the intervention period is 12 weeks)
Method of measurement
Enzymatic spectrophotometer method

5

Description
Total serum cholesterol
Timepoint
before the beginning of the study and immediately after the end of the study (the intervention period is 12 weeks)
Method of measurement
Enzymatic spectrophotometer method

6

Description
Serum high-density lipoprotein (LDL)
Timepoint
before the beginning of the study and immediately after the end of the study (the intervention period is 12 weeks)
Method of measurement
Enzymatic spectrophotometer method

7

Description
Serum low-density lipoprotein (LDL)
Timepoint
before the beginning of the study and immediately after the end of the study (the intervention period is 12 weeks)
Method of measurement
Enzymatic spectrophotometer method

8

Description
Body weight
Timepoint
before the beginning of the study and immediately after the end of the study (the intervention period is 12 weeks)
Method of measurement
Body analyzer

9

Description
Height
Timepoint
before the beginning of the study and immediately after the end of the study (the intervention period is 12 weeks)
Method of measurement
height gauge

10

Description
body mass index (BMI) Z-score

Timepoint
before the beginning of the study and immediately after the end of the study (the intervention period is 12 weeks)
Method of measurement
weight divided by height squared Z-score

11

Description
The percentage and amount of body fat mass
Timepoint
before the beginning of the study and immediately after the end of the study (the intervention period is 12 weeks)
Method of measurement
Body analyzer

12

Description
The percentage and amount of body fat-free mass
Timepoint
before the beginning of the study and immediately after the end of the study (the intervention period is 12 weeks)
Method of measurement
Body analyzer

13

Description
The percentage and amount of body water
Timepoint
before the beginning of the study and immediately after the end of the study (the intervention period is 12 weeks)
Method of measurement
Body analyzer

Intervention groups

1

Description
Intervention group: receiving a low-carbohydrate diet with restricted calories for 12 weeks (percentage distribution of macronutrients for carbohydrates, protein and fat is equal to 50, 25 and 25%, respectively)
Category
Lifestyle

2

Description
Control group: receiving a standard diet with restricted calories for 12 weeks
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Tehran Children's Medical Center Hospital
Full name of responsible person
Maryam Mahmoudi
Street address
Children's Medical Center, No. 62, next to Imam Khomeini Hospital, Dr. Mohammad Gharib St., at the end of Keshavarz Blvd., Tehran.
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Web page address
https://chmc.tums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mrs. Rostamabadi
Street address
Keshavarz Blvd., Corner of Qods St., Headquarters of Tehran University of Medical Sciences, 6th Floor, Room 605, Research and Technology Affairs Management Unit
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Phone
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research@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
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

Tehran University of Medical Sciences

Full name of responsible person

Maryam Mahmoudi

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

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Position

Student

Latest degree

Bachelor

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