Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Sep 2026

Evaluation of the effects of a low free sugar diet on lipid profile, glycemic indices, liver enzymes, inflammatory factors and hepatic steatosis and fibrosis in patients with Nonalcoholic fatty liver disease

Protocol summary

Study aim

Evaluate the effects of a low free sugar diet on lipid profile, glycemic indices, liver enzymes, inflammatory factors and hepatic steatosis and fibrosis in patients with Nonalcoholic fatty liver disease.

Design

Randomized clinical trials with control groups, parallel groups are performed on 42 patients.

Settings and conduct

In this study, adults with non-alcoholic fatty liver disease referred to Taleghani Hospital's Liver Clinic, who have the criteria to enter the study, if they desire to participate in this research with steatosis in ultrasound or fibroscan; general and activity questionnaires, anthropometric indicators are collected. At the beginning and end of the study, fibroscan and blood tests will be performed to evaluate the indicators.

Participants/Inclusion and exclusion criteria

People who desire to participate in the study with age 18-60 years and BMI above 20 who have evidence of non-alcoholic steatohepatitis in ultrasound or fibroscan and no history of alcohol consumption or Alcohol consumption less than 10 grams per day in women and less than 20 grams per day in men in the absence of other chronic and acute liver diseases and disorders, biliary tract disease, autoimmune diseases, cancer and hereditary disorders affecting Liver status and liver cirrhosis, lack of pregnancy or lactation in women, and non-use of hepatotoxic drugs are included in the study, and if they do not want to continue studying or using hepatotoxic drugs during the study or non-compliance with the diet, they will be excluded.

Intervention groups

Each person is randomly assigned to a low free sugar diet or a regular diet group with a dietary recommendation based on the classification.

Main outcome variables

Hepatic fibrosis, and steatosis Lipid profile, Glycemic indices, Liver enzymes, Inflammatory factors

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100524004010N30**
Registration date: **2020-06-11, 1399/03/22**
Registration timing: **registered_while_recruiting**

Last update: **2020-06-11, 1399/03/22**
Update count: **0**

Registration date

2020-06-11, 1399/03/22

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

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-07-23, 1398/05/01

Expected recruitment end date

2020-06-30, 1399/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effects of a low free sugar diet on lipid profile, glycemic indices, liver enzymes, inflammatory factors and hepatic steatosis and fibrosis in patients with Nonalcoholic fatty liver disease

Public title

Evaluation of the effects of a low free sugar diet in patients with Nonalcoholic fatty liver disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The desire to participate in research Age 60-18 years BMI above 20 Evidence of non-alcoholic steatohepatitis (inflammation and swelling of hepatocytes) second and third degree in ultrasonography Evidence of non-alcoholic steatohepatitis in fibro-scan results with CAP Score over 263 Lack of a history of alcohol consumption or alcohol consumption less than 10 grams per day in women and less than 20 grams per day in men Lack of other chronic and acute liver diseases and disorders (hepatitis B, C, etc.), biliary disease, autoimmune diseases, cancer and hereditary disorders affecting the condition of the liver (iron, copper storage disease) and cirrhosis Lack of pregnancy or lactation in women No consumption of hepatotoxic drugs such as phenytoin, tamoxifen and lithium, and drugs that affect liver function

Exclusion criteria:

Lack of desire to continue research Forced to use antibiotics or hepatotoxic drugs during the study Non-compliance with low free sugar diet

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study، in order to the randomization process، a simple randomization is used by using a table of random numbers. before beginning the study،each person is placed in one of the intervention or control groups based on a simple random division table. we have considered a two-digit code for the number of sample size numbers, and selected the start point by referring to the table, and based on the adjacent two-digit number, moved in the direction of the row, and we choose the first two-digit number less than 50 as the first sample and we'll continue to do this until the samples reach 50.

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 the National Institute of Nutritional Research and Food Industry

Street address

No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town

City

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Province

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Postal code

1981619573

Approval date

2020-01-05, 1398/10/15

Ethics committee reference number

IR.SBMU.NNFTRI.REC.1399.011

Health conditions studied

1

Description of health condition studied

Nonalcoholic fatty liver disease

ICD-10 code

ICD-10 code description

low free sugar diet, lipid profile, glycemic indices, liver enzymes, inflammatory factors, hepatic steatosis , fibrosis , patients with Nonalcoholic fatty liver disease

Primary outcomes

1

Description

Hepatic steatosis, Liver fibrosis

Timepoint

At the first and at the 12th week of the study

Method of measurement

Fibroscan

Secondary outcomes

1

Description
Weight
Timepoint
At the first , 6th and 12th week of the study
Method of measurement
Scale

2

Description
BMI
Timepoint
At the first , 6th and 12th week of the study
Method of measurement
Calculate

3

Description
Waist to hip ratio
Timepoint
At the first , 6th and 12th week of the study
Method of measurement
Calculate

4

Description
liver enzymes (AST,ALT,GGT)
Timepoint
At the first and at the 12th week of the study
Method of measurement
Enzymatic method

5

Description
lipid profile (TG,Total cholesterol,LDL-C,HDL-C)
Timepoint
At the first and at the 12th week of the study
Method of measurement
Enzymatic method

6

Description
FBS
Timepoint
At the first and at the 12th week of the study
Method of measurement
Enzymatic method

7

Description
Insulin
Timepoint
At the first and at the 12th week of the study
Method of measurement
Radioimmunoassay

8

Description
hs-CRP
Timepoint
At the first and at the 12th week of the study
Method of measurement
ELISA

9

Description
TNF-α
Timepoint
At the first and at the 12th week of the study
Method of measurement
ELISA

10

Description
NF-κB
Timepoint
At the first and at the 12th week of the study
Method of measurement
ELISA

11

Description
HOMA-IR
Timepoint
At the first and at the 12th week of the study
Method of measurement
Calculate

12

Description
QUICKI
Timepoint
At the first and at the 12th week of the study
Method of measurement
Calculate

Intervention groups

1

Description
Intervention group: a low free sugar diet with dietary and physical activity recommendations/12 weeks
Category
Lifestyle

2

Description
Control group: Dietary and physical activity recommendations/12 weeks
Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Gastroenterology and Liver Clinic of Taleghani Hospital

Full name of responsible person
Azita Hekmatdoost

Street address
Tabnak St. Velenjak Region, Chamran High Way, Tehran, Iran

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1985717413

Phone
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Email
a_hekmat2000@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Azita Hekmatdoost

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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 hekmatdoost

Position
Associate professor

Latest degree
Ph.D.

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