

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 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

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

#### 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

#### 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

##### Email address

hekmat@sina.tums.ac.ir

##### 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**

Tehran

**Province**

Tehran

**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- $\alpha$

### **Timepoint**

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

### **Method of measurement**

ELISA

## 10

### **Description**

NF- $\kappa$ B

### **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

**City**

Tehran

**Province**

Tehran

**Postal code**

1985717413

**Phone**

+98 21 2235 7484

**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

**Street address**

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

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**Email**

a\_hekmat2000@yahoo.com

**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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## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

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**Full name of responsible person**

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## Person responsible for updating data

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Shahid Beheshti University of Medical Sciences

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azita hekmatdoost

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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