

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation of the effects of Fasting Mimicking Diet (FMD) Combined with a Low-Sugar Diet on lipid profile, glycemic, inflammatory and histologic indices in Non-Alcoholic Fatty Liver (NAFLD): a randomized control trial

#### Protocol summary

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

#### Study aim

Determining the effect of fasting diet (5: 2) and 8.16 fasting diet combined with a Low-Sugar Diet in comparison with the control group on some metabolic factors, inflammation, steatosis and liver fibrosis in patients with non-alcoholic fatty liver

#### Design

Randomized clinical trials with control groups, parallel groups are performed on 75 patients

#### Settings and conduct

In this study, adults with non-alcoholic fatty liver disease referred to liver clinic of Taleghani hospital, who have the criteria to enter the study, if they desire to participate in this research fill out general and activity questionnaires and anthropometric indicators are collected. At the beginning and end of the study, fibroscan and blood tests are performed to evaluate the indicators

#### Participants/Inclusion and exclusion criteria

People who desire to participate in the study; age 18-50 years; BMI above 25 who have evidence of non-alcoholic steatohepatitis in ultrasound or fibroscan; 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; 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; no use of hepatotoxic drugs are included in the study. If they do not want to continue studying or using hepatotoxic drugs during the study or non-compliance with the diet, they are excluded.

#### Intervention groups

1- Control 2-fasting diet (5 /2) 3- intermittent-fasting diet 8/16 combined with a Low-Sugar Diet

#### Main outcome variables

#### General information

##### Reason for update

Update the variables

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20100524004010N31**

Registration date: **2020-08-19, 1399/05/29**

Registration timing: **prospective**

Last update: **2022-04-23, 1401/02/03**

Update count: **2**

##### Registration date

2020-08-19, 1399/05/29

##### 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

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###### Email address

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##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-09-22, 1399/07/01

##### Expected recruitment end date

2021-09-23, 1400/07/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Evaluation of the effects of Fasting Mimicking Diet (FMD) Combined with a Low-Sugar Diet on lipid profile, glycemic, inflammatory and histologic indices in Non-Alcoholic Fatty Liver (NAFLD): a randomized control trial

**Public title**

Evaluation of the effects of Fasting Mimicking Diet (FMD) Combined with a Low-Sugar Diet on lipid profile, glycemic, inflammatory and histologic indices in Non-Alcoholic Fatty Liver (NAFLD): a randomized control trial

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

General desire to participate in the study Age 50-30 years - Has evidence of non-alcoholic steatohepatitis and CAP score more than 263 Body mass index (BMI)  $\geq$  25kg / m<sup>2</sup> No history of alcohol consumption Lack of other diseases and chronic and acute liver disorders (hepatitis B, C, etc.), biliary disease, known autoimmune diseases and hereditary disorders affecting the condition of the liver (iron, copper and ... ) No pregnancy or breastfeeding in women Do not take hepatotoxic drugs such as phenytoin, amoxifen and lithium Do not take antibiotics for more than a week during or before the study period Do not consume Milk thistle(Silybum marianum) Lack of chronic inflammatory disease No history of cancer Lack of treatment with anti-inflammatory drugs Lack of recent weight loss diet Blood pressure less than 90/160 mmHg No kidney disease (GFR greater than 60 or creatinine between 7-1.4) No weight loss of more than 8% in the last 6 months Do not use weight loss drugs (chemical drugs and effective herbal products)

**Exclusion criteria:**

Changes in medications (lipid-lowering drugs, blood sugar control drugs, and blood pressure medications) during the study period Lack of adherence to the diet given to patients Take supplements or substances that change the individual effect of the diet during the intervention.

**Age**From **18 years** old to **50 years** old**Gender**

Both

**Phase**

N/A

**Groups that have been masked***No information***Sample size**Target sample size: **75****Randomization (investigator's opinion)**

Randomized

**Randomization description**

The first step is to create a random sequence number. For this purpose, we will use a random number generator on Stattek (<https://stattrek.com/statistics/random-number-generator.aspx>) for 75 numbers range from 1 to 3 (for example: 2 1 3 1 2 1 2 1 1 3 3 3 3 2 2 3 2 3 1 1 2 2 3 3 1 2 2.....). Then, we will specify the numbers to the groups for example, 1 will be assigned to the intervention group one (fasting diet 2/5), the numbers 2 to the intervention group two (fasting diet 8/16 combined with a low-sugar ediet ), the numbers 3 to the control group. Each number will represent a group according to the defined numbers. With this method, we will have a specific sequence of 75 codes of 1, 2, 3 , which shows the first to seventy-fifth people who are going to be entered in the study in each group. We write the codes on a piece of paper and put them in an envelope to use during sampling. Thus, after reviewing the inclusion criteria and if the participants desire, we will enter each person included in the study according to our predetermined list.

**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**

2020-11-14, 1399/08/24

**Ethics committee reference number**

IR.SBMU.NNFTRI.REC.1399.019

**Health conditions studied****1****Description of health condition studied**

Nonalcoholic fatty liver disease

**ICD-10 code**

K75.81

**ICD-10 code description**

Nonalcoholic steatohepatitis (NASH)

**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 and 12th week of the study

**Method of measurement**

Scale

**2****Description**

BMI

**Timepoint**

At the first and 12th week of the study

**Method of measurement**

Calculate

**3****Description**

Waist to hip ratio

**Timepoint**

At the first and 12th week of the study

**Method of measurement**

Calculate

**4****Description**

liver enzymes (AST,ALT,GGT)

**Timepoint**

At the first and 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 12th week of the study

**Method of measurement**

Enzymatic method

**6****Description**

FBS

**Timepoint**

At the first and 12th week of the study

**Method of measurement**

Enzymatic method

**7****Description**

Insulin

**Timepoint**

At the first and 12th week of the study

**Method of measurement**

Radioimmunoassay

**8****Description**

hs-CRP

**Timepoint**

At the first and 12th week of the study

**Method of measurement**

ELISA

**9****Description**

CK-18

**Timepoint**

At the first and 12th week of the study

**Method of measurement**

ELISA

**10****Description**

HOMA-IR

**Timepoint**

At the first and 12th week of the study

**Method of measurement**

Calculate

**11****Description**

TAC

**Timepoint**

At the first and 12th week of the study

**Method of measurement**

ELISA

**Intervention groups****1****Description**

Control group: Dietary recommendations

**Category**

Lifestyle

## 2

### Description

Intervention group: fasting diet (5 days of normal diet and two consecutive days with 75% calorie restriction and permission to consume 25% of calories per person at a specific time, for example 12 to 16 am because it is easier to tolerate fasting)

### Category

Lifestyle

## 3

### Description

Intervention group combined with a Low-Sugar Diet :  
fasting diet 8/16: 16 hours a day in fasting diet for example 8 nights to 12 noon and 8 hours normal diet  
Combined with a Low-Sugar Diet

### 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

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##### Postal code

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##### 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

##### Street address

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

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##### Email

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##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor organization/entity?

No

##### 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

Assistant 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

Shahid Beheshti University of Medical Sciences

##### Full name of responsible person

Azita Hekmatdoost

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Assistant Professor

##### Latest degree

Ph.D.

**Other areas of specialty/work**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Azita Hekmatdoost

**Position**

Assistant Professor

**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