

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Aug 2026

### The effect of co-administration of Dietary Approaches To Stop Hypertension (DASH) and Intermittent Fasting (IF) diets on hepatic parameters, glucose homeostasis, lipid profile and inflammatory biomarkers in patients with Non-Alcoholic Fatty Liver Disease (NAFLD): a Randomized Control Trial

#### Protocol summary

##### Study aim

Determine the effect of co- administration of DASH and intermittent Fasting (16:8) on liver parameters, glucose homeostasis, blood lipids and inflammatory factors in patients with non-alcoholic fatty liver disease.

##### Design

Randomized clinical trials with control groups, parallel groups, phase 2 on 50 patients, and random number-producing software will be used for randomization.

##### Settings and conduct

50 patients with non-alcoholic fatty liver referred to medical centers who have the conditions to enter the study, they will be included in the study after having a fibroscan test and having a cap score above 260 and willing to participate in the study. At the beginning of the study, an informed consent form is completed for each patient. At the beginning and end of the study (after 12 weeks), fiber scan test, calculation of anthropometric characteristics, completion of physical activity questionnaire, 24-hour recall questionnaire for 3 days, including 2 non-holiday days and 1 holiday day, and taking a blood sample of 5 cc after 12 hours of fasting .

##### Participants/Inclusion and exclusion criteria

Entry conditions: Age over 18 years, with evidence of non-alcoholic steatohepatitis with CAP Score above 260, without chronic inflammatory disease. conditions of non-entry: pregnancy or use of birth control pills, unwillingness to participate in the study. Weight loss program in the last 3 months. History of weight loss surgery, uncontrolled diabetes, cardiovascular and kidney disease

##### Intervention groups

1- Control(receiving nutritional recommendation to control disease). 2- Intervention:16:8 Intermittent Fasting

diet: 16 hours a day in a Intermittent Fasting and get DASH diet in 8 hours of day.

##### Main outcome variables

Alanine transaminase, Aspartate aminotransferase, and Gamma-glutamyl transferase 'Hepatic steatosis and fibrosis' Lipid profile and index of insulin resistance and sensitivity

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20100524004010N39**

Registration date: **2023-07-22, 1402/04/31**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-07-22, 1402/04/31**

Update count: **0**

##### Registration date

2023-07-22, 1402/04/31

##### 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**  
2023-06-18, 1402/03/28

**Expected recruitment end date**  
2023-09-19, 1402/06/28

**Actual recruitment start date**  
empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
The effect of co-administration of Dietary Approaches To Stop Hypertension (DASH) and Intermittent Fasting (IF) diets on hepatic parameters, glucose homeostasis, lipid profile and inflammatory biomarkers in patients with Non-Alcoholic Fatty Liver Disease (NAFLD): a Randomized Control Trial

**Public title**  
The effect of co-administration of Dietary Approaches To Stop Hypertension (DASH) and Intermittent Fasting IF diets on patients with Non-Alcoholic Fatty Liver Disease (NAFLD): a Randomized Control Trial

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Age over 18 years Having evidence of non-alcoholic fatty liver in fibroscan (CAP score>260) Not having 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. Not taking drugs that affect blood lipids, metformin, vitamin E and ursodeoxycholic acid (UDCA) and hepatotoxic drugs such as phenytoin, amoxifen and lithium. Not having chronic and acute liver diseases (hepatitis B, C, etc.), biliary disease, known autoimmune diseases, cancer and hereditary disorders affecting the liver (iron, copper storage disease) No history of weight loss surgery, weight loss program in the last 3 months Non-adherence to special diets such as vegetarianism No history of uncontrolled thyroid disease Willingness to participate in the study Not having uncontrolled celiac disease, diabetes, cardiovascular disease, lung disease and kidney disease  
**Exclusion criteria:**  
History of weight loss surgery and weight loss program during the last 3 months Failure to accept study conditions Taking medicine or supplements that can affect the results Following special diets and vegetarianism during the last 3 months Pregnancy or breastfeeding in women or Using birth control pills

**Age**  
From 18 years old

**Gender**  
Both

**Phase**  
2-3

**Groups that have been masked**

*No information*

**Sample size**  
Target sample size: 50

**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 50 numbers ranging from 1 to 2 (for example 2 1 1 2 1 2 1 1 2 2 2 1 1 2 2 1 2 2.....). Then, we will specify the numbers to the groups, for example, 1 will be assigned to the intervention group, and the numbers 2 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 50 codes of 1, 2, which shows the first to 50th people who are going to be entered into 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 National Nutrition and Food Technology Research Institute (NNFTRI)  
**Street address**  
#7, Shahid Hafezi Ave, Farahzadi Blvd, Shahrak Gharb  
**City**  
Tehran  
**Province**  
Tehran  
**Postal code**  
1981619573

**Approval date**  
2023-06-14, 1402/03/24

**Ethics committee reference number**  
IR.SBMU.NNFTRI.REC.1402.006

**Health conditions studied**

## 1

### **Description of health condition studied**

Non-alcoholic fatty liver

### **ICD-10 code**

K76.0

### **ICD-10 code description**

Fatty (change of) liver, not elsewhere classified

## **Primary outcomes**

## 1

### **Description**

Level of steatosis and liver fibrosis

### **Timepoint**

At the beginning and 3 months after the start of the study

### **Method of measurement**

Fibroscan

## **Secondary outcomes**

## 1

### **Description**

lipid profile

### **Timepoint**

At the beginning of the study and at the end of the study (after 3 months)

### **Method of measurement**

blood sample

## 2

### **Description**

insulin sensitivity index

### **Timepoint**

At the beginning of the study and at the end of the study (after 3 months)

### **Method of measurement**

math formula

## 3

### **Description**

Insulin resistance index

### **Timepoint**

At the beginning of the study and at the end of the study (after 3 months)

### **Method of measurement**

math formula

## 4

### **Description**

Insulin concentration

### **Timepoint**

At the beginning of the study and at the end of the study (after 3 months)

### **Method of measurement**

blood sample

## 5

### **Description**

Anthropometric indices

### **Timepoint**

At the beginning of the study and at the end of the study (after 3 months)

### **Method of measurement**

Tape measure, scale and mathematical formula

## 6

### **Description**

blood pressure

### **Timepoint**

At the beginning of the study and at the end of the study (after 3 months)

### **Method of measurement**

Sphygmomanometer

## 7

### **Description**

high-sensitivity C-reactive protein

### **Timepoint**

At the beginning of the study and at the end of the study (after 3 months)

### **Method of measurement**

blood sample

## 8

### **Description**

liver enzymes alanine transaminase, aspartate aminotransferase, gamma-glutamyl transferase

### **Timepoint**

At the beginning of the study and at the end of the study (after 3 months)

### **Method of measurement**

blood sample

## **Intervention groups**

## 1

### **Description**

Intervention group :After calculating the amount of calories needed by each person using the Meflin formula, each person For 12 weeks, receiving the co-administration of DASH and intermittent fasting 16:8 diets . 16 hours of a day in intermittent fasting for example, from 8:00 PM to 12:00 noon the next day and 8 hours of receiving the DASH diet ,which includes the consumption of whole grains, 2 to 3 units of low-fat or fat-free dairy products, 7 to 8 units of fruits and vegetables, limiting saturated fats and sweets and sugar-sweetened drinks.

### **Category**

N/A

## 2

### **Description**

Control group: They receive nutritional recommendations to control the disease: Avoid consuming too much sugar, jam, honey, syrup, soft drinks, and other foods that contain sugar. These foods aggravate fatty liver. It should be noted that the consumption of alcoholic beverages can cause and aggravate the symptoms of fatty liver. Be sure to use different vegetables with meals.

#### Category

Lifestyle

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Taleghani Hospital

##### Full name of responsible person

Amir Sadeghi

##### Street address

Ayatollah Taleghani Educational Hospital , Araabi St, Yaman Ave, Chamran Highway, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

198571151

##### Phone

+98 21 2243 2560

##### Email

taleghanihospital@sbmu.ac.ir

## 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.Tehran

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##### Phone

+98 21 2207 7425

##### Email

a\_hekmat2000@yahoo.com

##### 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

Professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Nutrition

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

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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

##### Position

Professor

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**Person responsible for updating data**

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**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Azita Hekmatdoost

**Position**

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**Email**

a\_hekmat2000@yahoo.com

**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