Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

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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 studuy 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 Stattrek (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

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#7, Shahid Hafezi Ave, Farahzadi Blvd, Shahrak Gharb

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Province
Tehran

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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

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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?

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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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