

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 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

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

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

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

+98 21 2293 0824

Email address

hekmat@sina.tums.ac.ir

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) $\geq 25\text{kg} / \text{m}^2$ 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.

AgeFrom **18 years** old to **50 years** old**Gender**

Both

Phase

N/A

Groups that have been masked

No information

Sample sizeTarget 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

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

City

Tehran

Province

Tehran

Postal code

1981619573

Phone

+98 21 2235 7483

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

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

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

City

tehran

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Phone

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Email

a_hekmat2000@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

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Phone

+98 21 2235 7483

Email

a_hekmat2000@yahoo.com

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

Ph.D.

Other areas of specialty/work

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Province

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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