Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

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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) ≥ 25kg / m2 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 Stattrek (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
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Tehran
Province
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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
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Sponsors / Funding sources

1

Sponsor
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Full name of responsible person
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No. 7, West Arghavan Ave., Farahzadi Blvd., Qods Town
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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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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