Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of time-restricted feeding (TRF) combined with a Lacto-Ovo-Vegetarian (LOV) diet on anthropometric indices, body composition, hepatic parameters, glucose homeostasis, lipid profile and inflammatory biomarkers in overweight and obese patients with non-alcoholic fatty liver disease: a Randomized Control Trial

Protocol summary

Study aim

Determining the effect of combined administration of Time-Restricted Feeding (TRF 16:8) and Lacto-Ovo-Vegetarian diet on anthropometric indices, body composition, liver parameters, glucose homeostasis, lipid profile and inflammatory factors in overweight and obese patients with non-alcoholic fatty liver disease

Design

This study is a randomized clinical trial with a control group, with parallel groups, phase 3 on 46 patients, and random sequence software will be used for randomization.

Settings and conduct

In this study, among the patients with non-alcoholic fatty liver disease who referred to the Gastroenterology and Liver Clinic of Taleghani Hospital and their disease was confirmed by a specialist doctor, 46 people who have the inclusion criteria will be selected randomly and will be placed in the intervention group or control group. At the beginning and end of the study, blood samples will be taken from the participants and anthropometric parameters and body composition will be measured. After that, people will receive a diet plan or nutritional advice for a period of 3 months based on their group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age over 18 years, body mass index over 24.9, evidence of non-alcoholic steatohepatitis. Exclusion criteria: Pregnancy and lactation, history of receiving a diet plan or weight loss in the last 3 months, alcoholism, suffering from other chronic diseases such as liver, kidney, endocrine and cardiovascular diseases.

Intervention groups

1. Intervention: receiving a Lacto-Ovo-Vegetarian diet combined with the time-restricted feeding method [16:8] (16 hours fasting and 8 hours receiving a Lacto-Ovo-Vegetarian diet) 2. Control: receiving nutritional recommendations to control the disease

Main outcome variables

Weight and body mass index, liver fibrosis, lipid profile, liver enzymes, inflammatory factors (hs-CRP, TNF-α)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230821059213N1**
Registration date: **2023-09-06, 1402/06/15**
Registration timing: **registered_while_recruiting**

Last update: **2023-09-06, 1402/06/15**
Update count: **0**

Registration date

2023-09-06, 1402/06/15

Registrant information

Name

Mahshad Shafiee

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2023-08-23, 1402/06/01
Expected recruitment end date
2023-11-22, 1402/09/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of time-restricted feeding (TRF) combined with a Lacto-Ovo-Vegetarian (LOV) diet on anthropometric indices, body composition, hepatic parameters, glucose homeostasis, lipid profile and inflammatory biomarkers in overweight and obese patients with non-alcoholic fatty liver disease: a Randomized Control Trial

Public title
The effect of time-restricted feeding (TRF) combined with a Lacto-Ovo-Vegetarian (LOV) diet on controlling of non-alcoholic fatty liver disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age over 18 years Body mass index higher than 24.9 (BMI≥25) Having evidence of steatohepatitis and non-alcoholic fatty liver based on the confirmation of the attending physician and the patient's laboratory and ultrasound results 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 Willingness to participate in the study and ability to complete the study process
Exclusion criteria:
Having other chronic and acute liver diseases and disorders (hepatitis B, C, etc.), biliary disease, kidney diseases, endocrine disorders, confirmed autoimmune diseases, cancer and hereditary disorders affecting the liver (iron and copper storage disease) Having uncontrolled cardiovascular diseases, chronic inflammatory disease, diabetes and celiac disease Alcoholism or drug abuse Pregnancy or Lactation in women Consumption of hepatotoxic drugs such as phenytoin, amoxifen and lithium Consumption of fiber, omega-3 and antioxidant supplements during the last 3 months Consumption of weight loss drugs or supplements Following special weight loss diets during the last 3 months Losing more than 10% of body weight during the last 6 months Failure to accept study conditions
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **46**
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 Stat trek (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 Shahid Beheshti University of Medical Sciences
Street address
School of Nutrition Sciences & Food Technology., Hafezi Ave., Farahzadi Blvd., Qods town
City
Tehran
Province
Tehran
Postal code
1981619573
Approval date
2023-08-15, 1402/05/24
Ethics committee reference number
IR.SBMU.NNFTRI.REC.1402.037

Health conditions studied

1

Description of health condition studied

Non-alcoholic fatty liver disease

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description

Weight

Timepoint

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

Method of measurement

Scale

2

Description

Fibrosis index (FIB-4)

Timepoint

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

Method of measurement

Calculation

Secondary outcomes

1

Description

Body Mass Index (BMI)

Timepoint

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

Method of measurement

Calculation

2

Description

Fat Mass

Timepoint

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

Method of measurement

Bio Impedance Analyzer

3

Description

Fat Free Mass

Timepoint

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

Method of measurement

Bio Impedance Analyzer

4

Description

Fatty Liver Index (FLI)

Timepoint

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

Method of measurement

Calculation

5

Description

BARD score

Timepoint

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

Method of measurement

Calculation

6

Description

AST to Platelet Ratio Index (APRI)

Timepoint

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

Method of measurement

Calculation

7

Description

Serum lipid profile (total cholesterol, triglyceride, HDL-C, LDL-C)

Timepoint

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

Method of measurement

Blood sample

8

Description

Liver enzymes (alanine aminotransferase, aspartate aminotransferase, gamma-glutamyl transferase)

Timepoint

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

Method of measurement

Blood sample

9

Description

Serum Insulin and Fasting Blood Sugar (FBS)

Timepoint

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

Method of measurement

Blood sample

10

Description
Insulin sensitivity index (QUICKI) and Insulin resistance index (HOMA-IR)
Timepoint
At the beginning and 3 months after the start of the study
Method of measurement
Calculation

11

Description
Tumor necrosis factor alpha (TNF-α)
Timepoint
At the beginning and 3 months after the start of the study
Method of measurement
Blood sample

12

Description
High-sensitivity C-reactive protein (hs-CRP)
Timepoint
At the beginning and 3 months after the start of the study
Method of measurement
Blood sample

Intervention groups

1

Description
Intervention group: Receiving a 3-month diet plan based on the personal energy requirement calculated according to the Mifflin formula and in the form of a combination of the 16:8 time-restricted feeding method, in which food intake is limited to an 8-hour period, followed by a 16-hour fasting period (for example, 8 pm to 12 noon) According to the fact that during the 16-hour fasting, it is free to drink non-caloric substances such as water, coffee and tea; And the lacto-ovo-vegetarian diet, in which the consumption of red meat, poultry, fish, and other products containing this group of foods is not allowed in this diet.
Category
Treatment - Other

2

Description
Control group: Receiving nutritional recommendations for disease control such as: Avoiding excessive consumption of sugar, jam, honey, syrup, soft drinks and other foods that contain sugar and alcoholic beverages. Avoiding high consumption of high-fat foods, oil and fried foods. And also Eating a variety of vegetables with meals.
Category
Lifestyle

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani hospital
Full name of responsible person
Dr. Amir Sadeghi
Street address
Ayatollah Taleghani Educational Hospital , Araabi St, Yaman Ave, Chamran Highway
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Shahid Beheshti University of Medical sciences- School of Nutrition
Full name of responsible person
Dr. Azita Hekmatdoost
Street address
School of Nutrition Sciences & Food Technology., Hafezi Ave., Farahzadi Blvd., Qods town
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Phone
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Email
a_hekmat2000@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Shahid Beheshti University of Medical sciences- School of Nutrition
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

Mahshad Shafiee

Position

MSc student of clinical nutrition

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

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Name of organization / entity

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Full name of responsible person

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Position

PhD of nutrition of Nutritional Sciences, Associate Professor

Latest degree

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Other areas of specialty/work

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Person responsible for updating data

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Position

MSc student of clinical nutrition

Latest degree

Bachelor

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