

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 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

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Mahshad Shafiee

Name of organization / entity

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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 $\geq$ 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

AgeFrom **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

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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

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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

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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
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MSc student of clinical 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