Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effects of intermittent fasting diet in comparison with low calorie diet on lipid profile, glycemic status and liver fibrosis in patients with non-alcoholic fatty liver

Protocol summary

Study aim

The effect of intermittent fasting diet in comparison with low calorie diet on lipid, glycemic and fibrosis parameters in patients with non-alcoholic fatty liver

Design

The present study will be a parallel clinical trial in which all people who are eligible to enter the study and volunteer to participate in the study will be given sufficient information about the objectives of the study, the type of intervention and the duration of the study. Prior to the intervention, individuals will be grouping based on body mass index (25-30 / 30-35) and gender (female / male). The genders will be matched.

Settings and conduct

Patients are randomly selected from those referred to Masoud Clinic in Tehran. The regimen delivered to patients in the control and intervention groups will be monitored for 12 weeks. At the beginning and end of the study, the main outcome variables are measured and compared to determine the effect of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria : 1) Age 50-20 years 2) Diagnosis of steatohepatitis based on cap-score> 263 3) People with hepatic fibrosis based on metavir-score ≤ F2 exclusion criteria : 1) Other acute and chronic liver diseases, autoimmune diseases, kidney diseases, biliary diseases, diabetes, cancer 2) use of hepatotoxic drugs

Intervention groups

In the intervention group, an intermittent fasting diet of the type (16: 8) will be used, in which individuals are allowed to receive only water and non-energy drinks for 16 hours (from 8 pm to 12 am the next day). Tea, coffee, and sugar-free chewing gum are free to eat for 8 hours (from 12 noon to 8 pm). People in the control group also receive a low-calorie diet, which ultimately reduces the total calculated energy by 300 kcal.

Main outcome variables

Blood sugar measurement, lipid profile and liver fibrosis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170202032367N5**
Registration date: **2022-03-05, 1400/12/14**
Registration timing: **prospective**

Last update: **2022-03-05, 1400/12/14**
Update count: **0**

Registration date

2022-03-05, 1400/12/14

Registrant information

Name

Hossien Imani

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-21, 1401/02/01

Expected recruitment end date

2022-10-23, 1401/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effects of intermittent fasting diet in comparison with low calorie diet on lipid profile, glycemic status and liver fibrosis in patients with non-alcoholic fatty liver

Public title

The effect of intermittent fasting diet on fatty liver

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 50-20 years Body mass index 25 - 30 kg/m2 Both genders Diagnosis of osteohepatitis based on Cap-score> 263 subjects with hepatic fibrosis based on Metavir-score ≤ F2 Willingness to cooperate

Exclusion criteria:

Consumption of alcohol Other acute and chronic liver diseases Autoimmune diseases, kidney diseases, biliary diseases, diabetes, cancer Pregnancy and lactation Use of hepatotoxic drugs (phenytoin, lithium, tamoxifen, antibiotics), weight loss drugs, sage and corticosteroids Follow a special diet in the last three months

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

Permuted Block Randomization method is used for randomization. In this method, eligible individuals with inclusion criteria are selected and then they are randomly selected using 4 blocks that block based on BMI (greater than 30 and between 25 and 30) and age (20-35 and 35-40 years old) will be assigned to one of the two groups of intermittent fasting diet and calorie restricted diet. In addition, to generate random sequences, we use online software for random generation software allocation Random, which perform simple or blocked random sequences.

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 Tehran University of Medical Sciences

Street address

Room 605, Sixth Floor, Central Building of Tehran University of Medical Sciences, Qods Street, Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

141556117

Approval date

2021-09-21, 1400/06/30

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1400.682

Health conditions studied

1

Description of health condition studied

fatty liver

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description

Fasting blood sugar

Timepoint

At the beginning and end of the study (after 12 weeks (84 days))

Method of measurement

Glucose oxidase enzymatic method using commercial kits of Pars Azmoon company in terms of (mg/dL)

2

Description

Total cholesterol

Timepoint

At the beginning and end of the study (after 12 weeks (84 days))

Method of measurement

Measurement of total cholesterol level using Pars Azmoon kits and auto analyzer

3

Description

Triglyceride

Timepoint
At the beginning and end of the study (after 12 weeks (84 days))
Method of measurement
Measurement of triglyceride level using Pars Azmoon kits and auto analyzer

4

Description
HDL cholesterol
Timepoint
At the beginning and end of the study (after 12 weeks (84 days))
Method of measurement
Measurement of HDL cholesterol level using Pars Azmoon kits and auto analyzer

5

Description
LDL cholesterol
Timepoint
At the beginning and end of the study (after 12 weeks (84 days))
Method of measurement
Measurement of LDL cholesterol by Friedwald formula [LDL = Chol - (TG / 5 + HDL)], with plasma triglyceride concentrations below 400 mg/dL.

6

Description
Aspartate transaminase enzyme (AST)
Timepoint
At the beginning and end of the study (after 12 weeks (84 days))
Method of measurement
Proposed IFCC method - Photometry Pars azmoon Kit

7

Description
Alanin transaminase enzyme (ALT)
Timepoint
At the beginning and end of the study (after 12 weeks (84 days))
Method of measurement
Proposed IFCC method - Photometry Pars azmoon Kit

8

Description
Gamma glutamyl transferase enzyme (GGT)
Timepoint
At the beginning and end of the study (after 12 weeks (84 days))
Method of measurement
Calorimetric-kinetic method proposed by IFCC

9

Description
Steatosis
Timepoint
At the beginning and end of the study (after 12 weeks (84 days))
Method of measurement
Fibroscan

10

Description
Hepatic fibrosis
Timepoint
At the beginning and end of the study (after 12 weeks (84 days))
Method of measurement
Fibroscan

11

Description
Fasting blood insulin level
Timepoint
At the beginning and end of the study (after 12 weeks (84 days))
Method of measurement
Special laboratory kit

12

Description
HOMA-IR
Timepoint
At the beginning and end of the study (after 12 weeks (84 days))
Method of measurement
Using the formula

13

Description
QUICKI
Timepoint
At the beginning and end of the study (after 12 weeks (84 days))
Method of measurement
Using the formula

14

Description
Weight
Timepoint
At the beginning and end of the study (after 12 weeks (84 days))
Method of measurement
Use digital scales with an accuracy of 0.1 kg and with minimal clothing and no shoes

15

Description
BMI
Timepoint

At the beginning and end of the study (after 12 weeks (84 days))

Method of measurement

Weight in kilograms divided by height squared in meters

16

Description

Waist circumference

Timepoint

At the beginning and end of the study (after 12 weeks (84 days))

Method of measurement

Tape meter

17

Description

Physical activity

Timepoint

At the beginning and end of the study (after 12 weeks (84 days))

Method of measurement

Record physical activity

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the intervention group, an intermittent fasting diet of the type (16: 8) will be used, in which individuals are allowed to receive only water and non-energy drinks for 16 hours (from 8 pm to 12 am the next day). Tea, coffee and sugar-free chewing gum are free to eat for 8 hours (from 12 noon to 8 pm).

Category

Treatment - Other

2

Description

Control group: People in the control group also receive a low-calorie diet (which is adjusted based on the history taken during the run-in period as well as the foods that are in the eating habits of the people). To adjust diet with a macronutrient ratio of 55% carbohydrate, 30% fat and 15% protein, first using the current age, sex, height and weight of patients in the Harris Benedict formula, the basal metabolic rate (BMR) of patients is calculated individually. Then, the total daily energy requirement of each person is calculated based on his physical activity and taking into account the thermogenic effect of food (TEF), and finally, the total calculated energy is reduced by 300 kcal. Based on these divisions, the required amounts from each food group will be calculated. The control group diet will be divided into six daily meals including 3 main meals and 3 snacks. Based on this, a food menu will be set up and the necessary alternatives will be taught to the people in the control group.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Masoud Clinic

Full name of responsible person

Hossein imani

Street address

No. 144, North Alley 19, Kargar St, Tehran

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Phone

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Web page address

https://www.masoudclinic.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Akbar Footohi

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msahrai@sina.tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Hossien Imani

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

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Position

Student

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Due to confidentiality of participant information, it is not possible to publish it

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not 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

Not applicable

Data Dictionary

Not applicable