

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jul 2026

The effect of oat consumption on hepatic and blood glucose control indices and lipid profile in patients with non-alcoholic fatty liver

Protocol summary

Study aim

assessing changes in fasting blood sugar, insulin, total cholesterol, LDL, HDL, triglycerides, alanine aminotransferase, aspartate aminotransferase, Homeostasis Model Assessment Insulin Resistance (HOMA-IR), and Quantitative Insulin Sensitivity Check Index (QUICKI) after 90 days Oat consumption and adherence to diet in the intervention group compared to the control group.

Design

A parallel-group, open-label, randomized controlled clinical trial of 80 patients. Randomized with stratified randomization based on BMI

Settings and conduct

People referring to a gastroenterology office, and receiving study information, were included in the study. After measuring the height and weight and completing the questionnaires, After blood sampling the diet and if they are in the intervention group, they will receive oats for 6 weeks. In the sixth week, they return to the clinic to receive oats (intervention group), measure their weight, and deliver food records. The study ends in the twelfth week after blood sampling and reweighing. The people who check the blood samples are blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: fatty liver patients over 18 years, liver enzyme between normal up to 2 times the average level, not alcohol consumption, not pregnant and breastfeeding, not suffering from cirrhosis, not following a diet, not Having malignancy and underlying disease, not using insulin, BMI between 25-40 kg/m² Exclusion criteria: unwillingness to consume oats, change in medications.

Intervention groups

The intervention group consumes 50 grams of oats twice a day and follows a diet. In contrast, the control group only follows a diet according to their weight and physical activity.

Main outcome variables

changes in fasting blood sugar, insulin, total cholesterol, LDL, HDL, triglycerides, alanine aminotransferase, aspartate aminotransferase, HOMA-IR, and QUICKI index

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130903014551N12**

Registration date: **2023-01-18, 1401/10/28**

Registration timing: **prospective**

Last update: **2023-01-18, 1401/10/28**

Update count: **0**

Registration date

2023-01-18, 1401/10/28

Registrant information

Name

Mohammad Hossein Rouhani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-05, 1402/02/15

Expected recruitment end date

2023-08-23, 1402/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
The effect of oat consumption on hepatic and blood glucose control indices and lipid profile in patients with non-alcoholic fatty liver

Public title
Effect of Oat in patients with Non alcoholic fatty liver disease

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Grade 2,3,4 non alcoholic fatty liver disease by ultrasound The level of liver enzymes should be between normal up to 2 times than average level A person should not consume alcohol or use less than 30 grams for men and 20 grams for women Absence of pregnancy and breastfeeding Absence of liver cirrhosis Not following a special diet Absence of malignancy and underlying diseases Not taking insulin in diabetic patients BMI should be between 25-40 kg/m²

Exclusion criteria:
Reluctance to consume oats Starting a new drug or changing the dose of previous drugs related to fatty liver in the last two months

Age
From 18 years old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: 80

Randomization (investigator's opinion)
Randomized

Randomization description
People with NAFLD are equally divided into 2 intervention and control groups. By stratified randomization based on BMI (between 25 and 30 and greater than and equal to 30), people are placed in 2 intervention and control groups. Individuals are matched between intervention and control groups based on BMI.

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 Isfahan University of Medical Sciences

Street address

Esfahan University of Medical Sciences, Hezar Jerib street, Esfahan, Iran

City

esfahan

Province

Isfahan

Postal code

8174673461

Approval date

2023-01-16, 1401/10/26

Ethics committee reference number

IR.ARI.MUI.REC.1401.260

Health conditions studied

1

Description of health condition studied

Non alcoholic fatty liver disease

ICD-10 code

K76.0

ICD-10 code description

Nonalcoholic fatty liver disease

Primary outcomes

1

Description

Alanine amino transferase (ALT)

Timepoint

Measuring alanine aminotransferase before the intervention and At the end of the twelfth week

Method of measurement

Blood sample and autoanalyzer

2

Description

aspartate aminotransferase

Timepoint

Measuring aspartate aminotransferase before the intervention and At the end of the twelfth week

Method of measurement

Blood sample and autoanalyzer

3

Description

fasting blood glucose (FBS)

Timepoint

Measuring fasting blood glucose before the intervention and At the end of the twelfth week

Method of measurement

Blood sample and autoanalyzer

4**Description**

Insulin

Timepoint

Measuring Insulin before the intervention and At the end of the twelfth week

Method of measurement

Blood sample and autoanalyzer

5**Description**

Total Cholesterol

Timepoint

Measuring total Cholesterol before the intervention and At the end of the twelfth week

Method of measurement

Blood sample and autoanalyzer

6**Description**

Low density lipoprotein (LDL)

Timepoint

Measuring LDL before the intervention and At the end of the twelfth week

Method of measurement

Blood sample and autoanalyzer

7**Description**

High density lipoprotein (HDL)

Timepoint

Measuring HDL before the intervention and At the end of the twelfth week

Method of measurement

Blood sample and autoanalyzer

8**Description**

Triglyceride (TG)

Timepoint

Measuring TG before the intervention and At the end of the twelfth week

Method of measurement

Blood sample and autoanalyzer

9**Description**

Quantitative Insulin Sensitivity Check Index (QUICKI)

Timepoint

Measuring(QUICKI) before the intervention and At the end of the twelfth week

Method of measurement

$QUICKI = 1 / [\log \text{fasting insulin (FI)} + \log \text{fasting glucose (FG)}]$

10**Description**

Homeostasis Model Assessment Insulin Resistance (HOMA-IR)

Timepoint

Measuring (HOMA-IR) before the intervention and At the end of the twelfth week

Method of measurement

$HOMA-IR = \text{fasting insulin } (\mu\text{U/L}) \times \text{fasting glucose (nmol/L)} / 22.5$

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: For 12 weeks, 50 grams of oat powder should be consumed twice a day (25 grams) with 1 glass of water, milk, and dough. The time to consume oats is morning and evening between meals. Oat powder was prepared by Pakan Bazar Company. Also, people use a diet according to their BMI and physical activity. In order to adjust the diet for each person, the basic energy is calculated based on the Mifflin-St formula. Adjusted Ideal Body Weight (AIBW) is used to calculate a person's energy needs. In the prescribed diet, 50-55% of calories come from carbohydrates, 15-20% of calories come from protein, and 25-30% come from fat.

Category

Treatment - Other

2**Description**

Control group: For 12 weeks, people use a diet according to their BMI and physical activity. In order to adjust the diet for each person, the basic energy is calculated based on the Mifflin-St formula. Adjusted Ideal Body Weight (AIBW) is used to calculate a person's energy needs. In the prescribed diet, 50-55% of calories come from carbohydrates, 15-20% of calories come from protein, and 25-30% come from fat.

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Dr. Amrollah Ebrahimi' s office

Full name of responsible person

Dr. Amrollah Ebrahimi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Web page address
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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

Esfahan 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
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Mohammad Hossein Rouhani
Position

Assistant Professor
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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