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)

Phone

+98 31 3792 3183

Email address

s_m_rouhani2003@yahoo.com

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

Isfehan

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
QUIKI = 1 / [log fasting insulin (FI) + log 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 = fasting insulin (μU/L) x 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 Bazr 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
Street address
4th floor, Razi complex, Shams Abadi street, Esfahan
City
Esfahan

Province
Isfehan
Postal code
8134776539
Phone
+98 993 181 4461
Email
a_ev11@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Dr. Gholamreza Askari
Street address
Deputy of Research & Technology of Isfahan University of Medical Science, Hezar Jarib Street
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 8487
Fax
+98 31 3668 8487
Email
Askari@mui.ac.ir
Web page address
https://research.mui.ac.ir
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
Esfahan University of Medical Sciences
Full name of responsible person
Mohammad Hossein Rouhani
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Isfahan, Iran.
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3792 3183
Fax
+98 31 1668 2509
Email
s_m_rouhani2003@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mohammad Hossein Rouhani
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Isfahan, Iran.
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3792 3183
Fax
+98 31 1668 2509
Email
s_m_rouhani2003@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mohammad Hossein Rouhani
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition

Street address
Isfahan, Iran.
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3792 3183
Fax
+98 31 1668 2509
Email
s_m_rouhani2003@yahoo.com

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