Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Sep 2026

Evaluating the effects of replacing ghee with rapeseed oil on liver steatosis and enzymes, lipid profile, insulin resistance, and anthropometric measurements in patients with non-alcoholic fatty liver disease

Protocol summary

Study aim
Determining the effects of replacing ghee with rapeseed oil on liver steatosis and enzymes, lipid profile, insulin resistance, and anthropometric measurements in patients with non-alcoholic fatty liver disease

Design
Parallel randomized controlled trial

Settings and conduct
The present study aiming to evaluate The effects of replacing ghee with rapeseed oil on liver steatosis and enzymes, lipid profile, insulin resistance, and anthropometric measurements in patients with non-alcoholic fatty liver disease.This study will be conducted in imam khomeini teaching hospital in urmia. This study is a parallel randomized controlled trial. 110 Patients will be randomly allocated into two groups, including intervention group and the control group.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with non-alcoholic fatty liver disease more than 18 years from both sexes Patients with non-alcoholic fatty liver disease with a BMI less than 30 Patients with non-alcoholic fatty liver disease with daily ghee consumption of 3 to 8servings per day Exclusion criteria: special diets Pregnancy and lactation during the study Viral hepatitis Alcohol consumption or history of alcohol consumption Diabetes mellitus Psychotic disorders Non-compliance to our recommendations regarding fat consumption Untreated hypothyroidism Renal Diseases Taking medications which increase GGT levels Heart failure and bone disease Alpha antitrypsin deficiency Gastrointestinal diseases such as celiac disease smoking Menopause Herbal therapy

Intervention groups
In the intervention group, in addition to the usual treatment, it will be recommended to change their fat intake to rapeseed oil. The control group will be advised to continue usual fat consumption.

Main outcome variables
liver steatosis; insulin resistance; liver enzymes; lipid profile; anthropometric measurements

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170206032417N5**
Registration date: **2022-01-18, 1400/10/28**
Registration timing: **prospective**

Last update: **2022-01-18, 1400/10/28**
Update count: **0**

Registration date
2022-01-18, 1400/10/28

Registrant information

Name
Mohammad Alizadeh

Name of organization / entity
Urmia University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2022-02-04, 1400/11/15

Expected recruitment end date
2022-08-06, 1401/05/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluating the effects of replacing ghee with rapeseed oil on liver steatosis and enzymes, lipid profile, insulin resistance, and anthropometric measurements in patients with non-alcoholic fatty liver disease

Public title
Effect of the type of oil on treatment of non-alcoholic fatty liver disease

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with non-alcoholic fatty liver disease more than18 years from both sexes Patients with non-alcoholic fatty liver disease with a BMI less than 30 Patients with non-alcoholic fatty liver disease with daily ghee consumption of 3 to 8 servings

Exclusion criteria:
special diets Pregnancy and lactation during the study Viral hepatitis Alcohol consumption or history of alcohol consumption Diabetes mellitus Psychotic disorders Non-compliance to our recommendations regarding fat consumption Untreated hypothyroidism Renal Diseases Taking medications which increase GGT levels Heart failure and bone disease Alpha antitrypsin deficiency Gastrointestinal diseases such as celiac disease smoking Menopause herbal therapy

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **110**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients with Non-Alcoholic Fatty liver disease referred to the gastroenterology clinic of Urmia Imam Khomeini Teaching Hospital will be selected consecutively on the basis of inclusion and exclusion criteria during the three months. The method will be used for randomization is the block randomization method to ensure that exactly the same number of participants will be randomly allocated to the intervention and control groups. In this method, one type of treatment is given to the first block and another type to the second block. The number of blocks will be two blocks due to two treatments.

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
Urmia University of Medical Sciences

Street address
Orjhans Street, Resalat Blvd, Urmia University of Medical Sciences

City
Urmia

Province
West Azarbaijan

Postal code
5714783734

Approval date
2021-11-10, 1400/08/19

Ethics committee reference number
IR.UMSU.REC.1400.355

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 weeks 0, 12

Method of measurement
Scale. kg

2

Description
Body mass index

Timepoint
At weeks 0, 12

Method of measurement
Weight(kg)/[height(m)]2 , kg/m2

3

Description
Gamma Glutamyl transferase
Timepoint
At weeks 0,12
Method of measurement
Enzymatic method , IU/ Lit

4

Description
ALP
Timepoint
At weeks 0, 12
Method of measurement
Enzymatic method , IU/ Lit

5

Description
Aspartat transaminase
Timepoint
At weeks 0, 12
Method of measurement
Enzymatic method, IU/Lit

6

Description
Alanine Aminotransferase
Timepoint
At weeks 0, 12
Method of measurement
Enzymatic method, IU/ Lit

7

Description
Fasting blood sugar
Timepoint
At weeks 0, 12
Method of measurement
Enzymatic method, IU/ Lit

8

Description
Serum insulin
Timepoint
At weeks 0, 12
Method of measurement
Radioimmunoassay

9

Description
Waist circumference
Timepoint
At weeks 0, 12
Method of measurement
Cm

10

Description
Hepatic steatosis
Timepoint
Before intervention and three month after intervention
Method of measurement
Ultrasonography

11

Description
HDL cholesterol
Timepoint
At weeks 0, 12
Method of measurement
Enzymatic method, mg/dl

12

Description
Triglyceride
Timepoint
At weeks 0, 12
Method of measurement
Enzymatic method, mg/dl

13

Description
LDL cholesterol
Timepoint
At weeks 0, 12
Method of measurement
Enzymatic method, mg/dl

14

Description
Total cholesterol
Timepoint
At weeks 0, 12
Method of measurement
Enzymatic method, mg/dl

15

Description
HOMA-IR
Timepoint
At weeks 0, 12
Method of measurement
Formula

16

Description
Height
Timepoint
Before intervention
Method of measurement
Before intervention

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The intervention group, in addition to the usual treatment, will be recommended to change their fat intake to rapeseed oil.
Category
Treatment - Other

2

Description
Control group: At first, people with daily consumption of 3 -8 servings or 15- 40 gr of ghee in cooking or flavoring will be selected. The control group, in addition to the usual treatment, will be advised to continue their usual fat consumption.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Teaching Hospital, Urmia
Full name of responsible person
Dr. Mohammad Reza mohammad hosseini azar
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Ershad Blvd, Ayatollah Modarres Blvd, Urmia
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Oroumia 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
Oroumia University of Medical Sciences
Full name of responsible person
Dr. Mohammad Alizadeh
Position
Professor in Nutrition
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Person responsible for updating data

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MSc Student of 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