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
Country
Iran (Islamic Republic of)
Phone
+98 44 3275 2375
Email address
alizadeh.m@umsu.ac.ir

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
Street address
Ershad Blvd, Ayatollah Modarres Blvd, Urmia
City
Urmia
Province
West Azarbaijan
Postal code
5431234567
Phone
+98 44 3567 8549
Email
hosseiniazar@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Dr Saber gholizadeh
Street address
Orjhans Street, Resalat Blvd, Urmia
City
Urmia
Province
West Azarbaijan
Postal code
5714783734
Phone
+98 21 8753 2210
Email
saber@umsu.ac.ir
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
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Department of Nutrition, School of Medicine, Urmia University of Medical Science, 11th km of Nazloo Highway, Urmia
City
Urmia
Province
West Azarbaijan
Postal code
5715799313
Phone
+98 44 3275 2375
Email
alizadeh.m@umsu.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Dr. Mohammad Alizadeh

Position
Ph.D in Nutrition/ Professor in Urmia University of Medical Sciences
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Department of Nutrition, School of Medicine, Urmia University of Medical Science, 11th km of Nazloo Highway, Urmia
City
Urmia
Province
West Azarbaijan
Postal code
5315799313
Phone
+98 44 3275 2375
Email
alizadeh.m@umsu.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Oroumia University of Medical Sciences
Full name of responsible person
Fatemeh Maleki Sedgi
Position
MSc Student of nutrition
Latest degree
Bachelor
Other areas of specialty/work
Nutrition
Street address
Department of Nutrition, School of Medicine, Urmia University of Medical Science, 11th km of Nazloo Highway, Urmia
City
Urmia
Province
West Azarbaijan
Postal code
5715799313
Phone
+98 44 3275 2375
Email
F.maleki1998@gmail.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