

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 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 8 servings 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 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 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

$\text{Weight(kg)/[height(m)]}^2$, 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