

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Aug 2026

Comparison of the effects of Camelina and Sunflower oils on metabolic, inflammatory and anti-inflammatory factors in patients with Non-alcoholic fatty liver

Protocol summary

Study aim

Comparison of the effects of Camelina and Sunflower oils on metabolic, inflammatory and anti-inflammatory factors in patients with Non-alcoholic fatty liver

Design

In this study, the target population will be those with NAFLD, who were included by a gastroenterologist with ultrasound examination based on inclusion criteria. After obtaining written consent the target population will be divided into camelina and Or the sunflower oil groups randomly. 15% of the total 30% of dietary fat should be allocated to mentioned oils.

Settings and conduct

This three-blind study is carried out at the Faculty of Nutrition, Tabriz University of Medical Sciences

Participants/Inclusion and exclusion criteria

Patients with NAFLD and lack of inclusion criteria (having other liver disease apart from NAFLD, liver transplant, pregnancy and lactation)

Intervention groups

Intervention (recipient of weight reduction diet + camelina oil) control (recipient of weight reduction diet + sunflower oil)

Main outcome variables

En Alanine amino transferase (ALT); aspartate amino transferase (AST); alkaline phosphatase (ALP); Degree of hepatic steatosis; fasting blood glucose; fasting insulin; insulin resistance; insulin sensitivity; total cholesterol (TC); low triglyceride High density lipoprotein (HDL); tumor necrosis factor-alpha (TNF- α); high-sensitivity c-reactive protein (Hs-CRP); interleukin-10 (IL-10)

parameters were presented as a comprehensive study in this field. Unfortunately, before registering this project in the Iranian Registry of Clinical Trials due to financial constraints, some of the considered parameters were removed. Recently, due to the funding of the project via top researchers grant, researchers have re-added the deleted parameters to the project for a comprehensive study in this field.

Acronym

IRCT registration information

IRCT registration number: **IRCT20150205020965N5**

Registration date: **2019-12-13, 1398/09/22**

Registration timing: **registered_while_recruiting**

Last update: **2020-08-01, 1399/05/11**

Update count: **1**

Registration date

2019-12-13, 1398/09/22

Registrant information

Name

Parvin Dehghan

Name of organization / entity

Tabriz University Of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 41 3335 7580

Email address

dehghanp@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-20, 1398/08/29

Expected recruitment end date

2020-05-18, 1399/02/29

General information

Reason for update

According to the comprehensive review on registered trial, all the added parameters along with the recorded

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of Camelina and Sunflower oils on metabolic, inflammatory and anti-inflammatory factors in patients with Non-alcoholic fatty liver

Public title

The effect of camelina oil in patients with nonalcoholic fatty liver

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age range 20 to 65 years BMI $\geq$ 25 No weight changes over the past 3 months Restricted Consumption of edible nuts and fish Tendency to use camelina oil Having grade 1 and 2 of non-alcoholic fatty liver disease

Exclusion criteria:

Having other liver disease apart from NAFLD (alcoholic fatty liver, viral hepatitis, cirrhosis and biliary obstruction, liver cancer)) Liver transplantation Pregnancy and Lactation Kidney, Cardiovascular Disease Alcohol and tobacco consumption high physical activity having acute illness Use of drugs such as glucocorticoids, nonsteroidal anti-inflammatory drugs (NSAIDS), hepatotoxic drugs, antibiotics Use antioxidant supplements and W3 history of using weight loss diet or a special diet over the past 6 months

AgeFrom **20 years** old to **65 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample sizeTarget sample size: **46****Randomization (investigator's opinion)**

Randomized

Randomization description

Classification of these variables will be used to match them in BMI, age and sex. All of the 23 patients will be randomly divided into two groups including intervention (Weight loss diet+ Camelina oil) and control (Weight loss diet + Sunflower oil) by using RAS software which is dividing patients to 2 and 4 blocks, 1 and 2 codes will be given them respectively too.

Blinding (investigator's opinion)

Triple blinded

Blinding description

After randomizing, the same weight loss diets with similar recommendations will be given by a dietitian to

both groups. Both oils will be packaged in similar 900 grams opaque containers, without the researcher intervention and will be coding (1 and 2). The dietitian will introduce the oils by codes to patients. Until the reporting the results patient, researcher and analyser will not be aware of the codes. After the end of research, decodation will be done. So the study will be Triple-Blind.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Tabriz University of Medical Sciences

Street address

Central Building No. 2, Tabriz University of Medical Sciences, Golgasht Street, Tabriz

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Tabriz

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East Azarbaijan

Postal code

5166614711

Approval date

2019-10-20, 1398/07/28

Ethics committee reference number

IR.TBZMED.REC.1398.743

Health conditions studied**1****Description of health condition studied**

Non-alcoholic fatty liver

ICD-10 code

k76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes**1****Description**

ALT

Timepoint

At baseline and three months after baseline

Method of measurement

Hitachi 911 auto-analyzer

<u>2</u> Description AST Timepoint At baseline and three months after baseline Method of measurement Hitachi 911 auto-analyzer	<u>9</u> Description Total cholesterol Timepoint At baseline and three months after baseline Method of measurement Hitachi 911 auto-analyzer
<u>3</u> Description ALP Timepoint At baseline and three months after baseline Method of measurement Hitachi 911 auto-analyzer	<u>10</u> Description HDL-cholesterol Timepoint At baseline and three months after baseline Method of measurement Hitachi 911 auto-analyzer
<u>4</u> Description Degree of hepatic steatosis Timepoint At baseline and three months after baseline Method of measurement Ultrasound	<u>11</u> Description LDL-cholesterol Timepoint At baseline and three months after baseline Method of measurement calculation of LDL using friedewald equation
<u>5</u> Description Fasting glucose Timepoint At baseline and three months after baseline Method of measurement Hitachi 911 auto-analyzer	<u>12</u> Description Triglyceride Timepoint At baseline and three months after baseline Method of measurement Hitachi 911 auto-analyzer
<u>6</u> Description Insulin Sensitivity Index (QUICK) Timepoint At baseline and three months after baseline Method of measurement Computing	<u>13</u> Description Highly sensitive C-reactive protein(hs-CRP) Timepoint At baseline and three months after baseline Method of measurement ELISA Dedicated Kit
<u>7</u> Description Insulin Resistance Index (HOMA-IR) Timepoint At baseline and three months after baseline Method of measurement Computing	<u>14</u> Description Tumor Necrosis Factor(TNF) Timepoint At baseline and three months after baseline Method of measurement ELISA Dedicated Kit
<u>8</u> Description Fasting insulin Timepoint At baseline and three months after baseline Method of measurement Chemoluminescence	<u>15</u> Description Interleukin 10(IL10) Timepoint At baseline and three months after baseline Method of measurement ELISA Dedicated Kit

16

Description

Total antioxidant capacity

Timepoint

At baseline and three months after baseline

Method of measurement

kit

17

Description

Malondialdehyde

Timepoint

At baseline and three months after baseline

Method of measurement

kit

18

Description

superoxide dismutase

Timepoint

At baseline and three months after baseline

Method of measurement

kit

19

Description

Glutathione peroxidase

Timepoint

At baseline and three months after baseline

Method of measurement

kit

20

Description

8-iso-prostaglandin F2 α (8-iso-PGF2 α)

Timepoint

At baseline and three months after baseline

Method of measurement

kit

21

Description

leptin

Timepoint

At baseline and three months after baseline

Method of measurement

kit

22

Description

adiponectin

Timepoint

At baseline and three months after baseline

Method of measurement

kit

23

Description

ghrelin

Timepoint

At baseline and three months after baseline

Method of measurement

kit

24

Description

Appetite status

Timepoint

At baseline and three months after baseline

Method of measurement

questionnaire

25

Description

PPAR- α expression

Timepoint

At baseline and three months after baseline

Method of measurement

pcr

26

Description

mental health

Timepoint

At baseline and three months after baseline

Method of measurement

questionnaires

27

Description

lipopolysaccharide

Timepoint

At baseline and three months after baseline

Method of measurement

kit

28

Description

cd4

Timepoint

At baseline and three months after baseline

Method of measurement

kit

29

Description

IL17

Timepoint

At baseline and three months after baseline

Method of measurement

kit

30

Description

cd8

Timepoint

At baseline and three months after baseline

Method of measurement

kit

31

Description

ILB1

Timepoint

At baseline and three months after baseline

Method of measurement

kit

32

Description

Brain-derived Neurotrophic Factor

Timepoint

At baseline and three months after baseline

Method of measurement

kit

Secondary outcomes

1

Description

Body Mass Index (BMI)

Timepoint

At baseline and three months after baseline

Method of measurement

Scale-Meter

2

Description

Amount of received energy

Timepoint

At baseline and three months after baseline

Method of measurement

questionnaire

3

Description

Daily macronutrient intake (carbohydrate, protein, fat)

Timepoint

At baseline and three months after baseline

Method of measurement

questionnaire

4

Description

Waist circumference (WHR)

Timepoint

At baseline and three months after baseline

Method of measurement

Calculate by splitting waist to hip

5

Description

blood pressure

Timepoint

At baseline and three months after baseline

Method of measurement

Mercuric barometr

6

Description

Assessment of the body composition

Timepoint

At baseline and three months after baseline

Method of measurement

BIA devices

Intervention groups

1

Description

In this study, Camelina oil will be replaced with 15% of the daily total fat intake for three months. Then, 15 days before the beginning of study, FFQ questionnaire will be completed for selected patients based on inclusion and exclusion criteria to determine the dietary pattern of patients. Patients will also be asked not to use omega-3 oils (as mentioned in list), during this time. Then, basal energy expenditure of each person will be calculated by Mifflin equation based on their weight, age, sex and total energy expenditure will be calculated according to the person's daily physical activity. For losing weight, 500 kcal reduction of total energy expenditure will be done, and then macronutrients will be distributed to 50% carbohydrate, 30% fat, 20% protein, and the proper diet will be adjusted according to one's dietary pattern. 15% of the dietary fat will be provide by Camelina oil (prepared by cold press, rich in omega-3 fatty acids, then will be analyzed before intervention). Patients will be instructed to measure the recommended amount of oil with the modules given with the oil, and add it to their salad or meal every day (while consuming or cooking), and intake the remain amount from dairy fat, meat and other oils. The oils will be given monthly to patients, and they will be advised to keep the consuming oil inside the refrigerator, depending on the type of processing (cold press). Each week a phone call will be made to ensure adherence to the diet, oil intake, and patient status assessment will be done. Patients will be asked to deliver the remaining oil bottles each month to receive the new oil bottles for the following month to ensure consumption and following them up. Patients will be advised to avoid fried foods, simple carbohydrates, solid oils and will be advised to use steamed foods as much as possible. Patients will be asked to report any gastrointestinal problems or not possibility of oil intake to available numbers. Metabolic, biochemical, anthropometric parameters, blood pressure and dietary intakes will be

assessed before and after intervention.

Category

Treatment - Drugs

2

Description

In this study, Sunflower oil will be replaced with 15% of the daily total fat intake for three months. Then, 15 days before the beginning of study, FFQ questionnaire will be completed for selected patients based on inclusion and exclusion criteria to determine the dietary pattern of patients. Patients will also be asked not to use omega-3 oils (as mentioned in list), during this time. Then, basal energy expenditure of each person will be calculated by Mifflin equation based on their weight, age, sex and total energy expenditure will be calculated according to the person's daily physical activity. For losing weight, 500 kcal reduction of total energy expenditure will be done, and then macronutrients will be distributed to 50% carbohydrate, 30% fat, 20% protein, and the proper diet will be adjusted according to one's dietary pattern. 15% of the dietary fat will be provide by Sunflower oil (prepared by cold press, rich in omega-3 fatty acids, then will be analyzed before intervention). Patients will be instructed to measure the recommended amount of oil with the modules given with the oil, and add it to their salad or meal every day (while consuming or cooking), and intake the remain amount from dairy fat, meat and other oils. The oils will be given monthly to patients, and they will be advised to keep the consuming oil inside the refrigerator, depending on the type of processing (cold press). Each week a phone call will be made to ensure adherence to the diet, oil intake, and patient status assessment will be done. Patients will be asked to deliver the remaining oil bottles each month to receive the new oil bottles for the following month to ensure consumption and following them up. Patients will be advised to avoid fried foods, simple carbohydrates, solid oils and will be advised to use steamed foods as much as possible. Patients will be asked to report any gastrointestinal problems or not possibility of oil intake to available numbers. Metabolic, biochemical, anthropometric parameters, blood pressure and dietary intakes will be assessed before and after intervention.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz International Hospital

Full name of responsible person

Dr manoocher khoshbaten

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Professor Alireza Rahimi

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Faculty of Nutrition and Food Science, Tabriz University of Medical Sciences, Golgasht Street, Tabriz, Iran

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ostadrahimi@tbzmed.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Parvin Dehghan

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

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Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is 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

Title and more details about the data/document

Reporting the results

When the data will become available and for how long

After finishing and publishing the project articles

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

With the permission of the project researcher and the project sponsoring organization - University of Nutrition Research and Research Deputy

From where data/document is obtainable

Dr. Parvin Dehghan, Faculty of Nutrition and Food Sciences, Tabriz University of Medical Sciences
Email:Dehghan.nut@gmail.com +98 914 471 0299

What processes are involved for a request to access data/document

The applicator can send a request to the person responsible for the study by email.

Comments