Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

General information

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

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≥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
Age
From **20 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target 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
City
Tabriz
Province
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

2

Description
AST
Timepoint
At baseline and three months after baseline
Method of measurement
Hitachi 911 auto-analyzer

3

Description
ALP
Timepoint
At baseline and three months after baseline
Method of measurement
Hitachi 911 auto-analyzer

4

Description
Degree of hepatic steatosis
Timepoint
At baseline and three months after baseline
Method of measurement
Ultrasound

5

Description
Fasting glucose
Timepoint
At baseline and three months after baseline
Method of measurement
Hitachi 911 auto-analyzer

6

Description
Insulin Sensitivity Index (QUICK)
Timepoint
At baseline and three months after baseline
Method of measurement
Computing

7

Description
Insulin Resistance Index (HOMA-IR)
Timepoint
At baseline and three months after baseline
Method of measurement
Computing

8

Description
Fasting insulin
Timepoint
At baseline and three months after baseline
Method of measurement
Chemoluminescense

9

Description
Total cholestrol
Timepoint
At baseline and three months after baseline
Method of measurement
Hitachi 911 auto-analyzer

10

Description
HDL-cholesterol
Timepoint
At baseline and three months after baseline
Method of measurement
Hitachi 911 auto-analyzer

11

Description
LDL-cholesterol
Timepoint
At baseline and three months after baseline
Method of measurement
calculation of LDL using friedewald equation

12

Description
Triglyceride
Timepoint
At baseline and three months after baseline
Method of measurement
Hitachi 911 auto-analyzer

13

Description
Highly sensitive C-reactive protein(hs-CRP)
Timepoint
At baseline and three months after baseline
Method of measurement
ELISA Dedicated Kit

14

Description
Tumor Necrosis Factor(TNF)
Timepoint
At baseline and three months after baseline
Method of measurement
ELISA Dedicated Kit

15

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 F2α (8-iso-PGF2α)
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

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Full name of responsible person

Professor Alireza Rahimi

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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

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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Faculty of Nutrition and Food Science, Tabriz University of Medical Sciences, Golgasht Street, Tabriz, Iran
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Person responsible for scientific inquiries

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Person responsible for updating data

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Email
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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