Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Sep 2026

The effect of Camelina oil with and without Resistant dextrin supplementation on metabolic, inflammatory and anti-inflammatory markers in patients with Non-alcoholic fatty liver

Protocol summary

Study aim

Effect of Camelina oil with and without Resistant dextrin supplementation on metabolic, inflammatory, anti-inflammatory, immune markers and mental health in patients with Non-alcoholic fatty liver

Design

a triple blind randomized clinical trial with control group and parallel group. sample size is 32

Settings and conduct

This is a triple blind study in Tabriz University of Medical Sciences.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 20 to 65 years; BMI≥25; restriction of consumption of edible nuts and fish; propensity to consume camelina and prebiotic oil. Exclusion criteria:Having liver disease other than NAFLD (alcoholic fatty liver, viral hepatitis, cirrhosis and biliary obstruction, liver cancer); liver transplantation; pregnancy; lactation; Kidney; Cardiovascular; Alcohol; Cigarettes & Drugs; High Physical Activity; Acute Disease; Medications Like Glucocorticoids; Last month or special diet; reluctance to take prebiotics and gastrointestinal symptoms; Weight changes in the last 3 months

Intervention groups

Intervention group 1: (Weight loss diet + camelina oil + resistant dextrin + physical activity) Control group: (Weight loss diet + camelina oil + malt dextrin + physical activity)

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

No changes have been made in the protocol of the present study, and only some parameters have been added. 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: **IRCT20150205020965N4**
Registration date: **2019-12-13, 1398/09/22**
Registration timing: **registered_while_recruiting**

Last update: **2020-09-07, 1399/06/17**
Update count: **1**

Registration date

2019-12-13, 1398/09/22

Registrant information

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2019-11-15, 1398/08/24

Expected recruitment end date
2020-05-13, 1399/02/24

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of Camelina oil with and without Resistant dextrin supplementation on metabolic, inflammatory and anti-inflammatory markers in patients with Non-alcoholic fatty liver

Public title
The effect of Camelina oil with and without Resistant dextrin supplementation on Non-alcoholic fatty liver

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age range 20 to 65 years BMI≥25 Edible nuts and fish consumption restriction Tendency to use camelina oil and prebiotic Having grade 1 and 2 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, Lactation Having kidney, Cardiovascular Disease Alcohol Consumption and smoking High physical activity Having acute illness Use of drugs such as glucocorticoids, nonsteroidal anti-inflammatory drugs (NSAIDS), hepatotoxic drugs, antibiotics Taking antioxidant supplements and W3 history of losing weight over the past 6 months or a special diet Unwillingness to use prebiotics Gastrointestinal symptoms incidence during the study Weight changes over the past 3 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: **32**

Randomization (investigator's opinion)
Randomized

Randomization description
At baseline, eligible individuals will be matched for BMI, age, and sex according to the classification of these variables. Individuals will be randomly divided into two groups of 16 intervention (receiving weight loss diet + Camelina oil +Maltodextrin) control (recipient). Weight loss regimen + Camelina oil + Resistant dextrin) divided into 2 and 4 blocks using RAS software and will be given codes 1 and 2.

Blinding (investigator's opinion)
Triple blinded

Blinding description
After randomization, both groups will be fed the camilina oil with identical weight loss regimens with similar recommendations by the expert. Resistant dextrin and maltodextrin will also be encoded in sachets weighing 5 g in similar packages (metallized) by the researcher and coded with codes 1 and 2. Nutritionists will introduce code to patients when giving diet and oil, resistant dextrin and malt dextrin. Until the patient study results are released, the researcher and data analyzer will not be aware of the assigned codes. So the study will be three-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.1398.738

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
sonography

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
calculation

7

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

8

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

9

Description
Total -cholesterol
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

12

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

13

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

14

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

15

Description
Interleukin 10(IL10)
Timepoint
At baseline and three months after baseline
Method of measurement
ELISA 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
8-iso-prostaglandin F2α (8-iso-PGF2α)
Timepoint
At baseline and three months after baseline
Method of measurement
kit

19

Description
superoxide dismutase
Timepoint
At baseline and three months after baseline
Method of measurement
kit

20

Description
leptin
Timepoint
At baseline and three months after baseline
Method of measurement
kit

21

Description
adiponectin
Timepoint
At baseline and three months after baseline
Method of measurement
kit

22

Description
ghrelin
Timepoint
At baseline and three months after baseline
Method of measurement
kit

23

Description
PPAR-α expression
Timepoint
At baseline and three months after baseline
Method of measurement
kit

24

Description
mental health
Timepoint
At baseline and three months after baseline
Method of measurement
questionnaires

25

Description
lipopolysaccharide
Timepoint
At baseline and three months after baseline
Method of measurement
kit

26

Description
cd4
Timepoint
At baseline and three months after baseline
Method of measurement
kit

27

Description
cd8
Timepoint
At baseline and three months after baseline
Method of measurement
kit

28

Description
ILB1
Timepoint
At baseline and three months after baseline
Method of measurement
kit

29

Description
Brain-derived Neurotrophic Factor
Timepoint
At baseline and three months after baseline
Method of measurement
kit

30

Description
il17
Timepoint
At baseline and three months after baseline
Method of measurement
kit

31

Description
PPAR-α expression
Timepoint
At baseline and three months after baseline
Method of measurement
pcr

Secondary outcomes

1

Description
Body Mass Index (BMI)
Timepoint
At baseline and three months after baseline
Method of measurement
Calculation

2

Description
Amount of received energy
Timepoint
At baseline and three months after baseline
Method of measurement
Questionnaire

3

Description
Daily carbohydrate intake
Timepoint
At baseline and three months after baseline
Method of measurement
Questionnaire

4

Description
Daily protein intake
Timepoint
At baseline and three months after baseline
Method of measurement
Questionnaire

5

Description
Daily fat intake
Timepoint
At baseline and three months after baseline
Method of measurement
Questionnaire

6

Description
Daily fiber intake
Timepoint
At baseline and three months after baseline
Method of measurement
Questionnaire

7

Description
Weight
Timepoint
At baseline and three months after baseline
Method of measurement
Scale

8

Description
Waist circumference (WC)
Timepoint
At baseline and three months after baseline
Method of measurement
Tape

9

Description
Hip circumference (HC)
Timepoint
At baseline and three months after baseline
Method of measurement
Tape

10

Description
Waist circumference (WHR)

Timepoint
At baseline and three months after baseline
Method of measurement
Calculation

11

Description
Blood pressure
Timepoint
At baseline and three months after baseline
Method of measurement

Mercury barometer

Treatment - Other

12

Description

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 and patients will receive two of 5-mg dextrin-resistant doses every day 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) ,prebiotic and probiotic sources 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. At the same time, patients will be advised to dissolve one serving of powdered sachets (resistant dextrin) in the lukewarm water each time and consume it by food in the morning and night. The oils and powder supplements 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, supplement intake, and patient status assessment will be done. Patients will be asked to deliver the remaining oil and sachet bottles each month to receive the new oil and sachet 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

2

Description

In this study, Camelina oil will be replaced with 15% of the daily total fat intake and patients will receive two of 5-mg maltodextrin doses every day 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) ,prebiotic and probiotic sources 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. At the same time, patients will be advised to dissolve one serving of powdered sachets (maltodextrin) in the lukewarm water each time and consume it by food in the morning and night. The oils and powder supplements 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, supplement intake, and patient status assessment will be done. Patients will be asked to deliver the remaining oil and sachet bottles each month to receive the new oil and sachet 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.Manouchehr Khoshbaten

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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
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
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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 the study and publishing the project articles

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

with permission of Project Researcher and Project Sponsor - Nutrition Research Center

From where data/document is obtainable

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

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

The applicant can send an application to the responsible person by email

Comments