

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Aug 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 $\geq$ 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

Name

Parvin Dehghan

Name of organization / entity

Tabriz University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 3335 7580

Email address

dehghanp@tbzmed.ac.ir

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 $\geq$ 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 camelina 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 F2 α (8-iso-PGF2 α)

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

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 provided 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 provided 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

Street address

Tabriz International Hospital, First of Zaffaraniyeh,
Aflaknema Square

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Phone

+98 41 3332 8832

Email

mkhoshbaten@yahoo.com

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Tabriz University of Medical Sciences

Full name of responsible person

Professor Alireza Ostad Rahimi

Street address

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

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Phone

+98 41 3335 7581

Email

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

Street address

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

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Phone

+98 41333340634

Email

dehghan.nut@gmail.com

Person responsible for scientific 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

Street address

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

City

Tabriz

Province

East Azarbaijan

Postal code

5165665931

Phone

+98 41333340634

Email

Dehghan.nut@gmail.com

Person responsible for updating data

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

Street address

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

City

Tabriz

Province

East Azarbaijan

Postal code

5165665931

Phone

+98 41 3334 0634

Email

Dehghan.nut@gmail.com

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