# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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**
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**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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**Full name of responsible person**
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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**
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**Full name of responsible person**
Parvin Dehghan
**Position**
Associate professor
**Latest degree**
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**Other areas of specialty/work**
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## Person responsible for updating data

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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**