Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Nov 2026

Investigating the effect of Bane (Pistacia atlantica sub. Kurdica) gum oral supplement on the improvement of oxidant/ antioxidant and inflammatory indices, and Keap1/Nrf-2/ARE signaling pathway in patients with non-alcoholic fatty liver disease: A Randomized Clinical Trial

Protocol summary

Study aim

Determining the effect of Bane gum on fatty liver

Design

This study will be a three-blind, placebo-controlled, parallel-group, phase 3 clinical trial on 46 patients, and blocking design will be used for randomization.

Settings and conduct

This study will be conducted at the Faculty of Nutritional Sciences and Food Technology of Kermanshah University of Medical Sciences- Iran. Completing the physical activity questionnaires and 3-day food record will be done at the beginning of the study, in the middle of the study and at the end of the study. In addition to the measurement of anthropometric indices, body composition and blood pressure at the beginning and end of the study, 10 cc of venous blood will be taken from all patients fasting for 10-12 hours to perform serum tests and expression of the desired genes.

Participants/Inclusion and exclusion criteria

Inclusion criteria include Grade 1 and 2 fatty liver and non-entry conditions include having gastrointestinal, liver (fibrosis, cirrhosis, HCC), autoimmune, kidney, thyroid and cardiovascular diseases.

Intervention groups

People with grade 1 and 2 fatty liver will be randomly divided into placebo (n=21) and supplement (n=21) groups. Patients in the supplement group were given 2 tablespoons of oral emulsion every 12 hours, each spoon containing 500 mg of Pistacia atlantica gum. Patients in the placebo group will receive 2 tablespoons of oral emulsion with the same appearance as the supplement every 12 hours. Also, people of both groups are subjected to a weight loss diet of 250 kilocalories, reducing the amount of energy needed daily. The duration of the intervention will be 8 weeks.

Main outcome variables

- Oxidative stress indicators (MDA, TAC, TOS) - Gene expression of antioxidant enzymes (NQO1, HMOX-1, GCLC) - Nrf-2 gene expression - Serum levels of inflammatory and anti-inflammatory factors (IL-10, IL-6)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231219060466N1**
Registration date: **2024-01-05, 1402/10/15**
Registration timing: **retrospective**

Last update: **2024-01-05, 1402/10/15**
Update count: **0**

Registration date

2024-01-05, 1402/10/15

Registrant information

Name

Roghayeh Mostafaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 83 3827 0803

Email address

r_mostafai@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-22, 1402/10/01

Expected recruitment end date

2023-12-31, 1402/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of Bane (Pistacia atlantica sub. Kurdica) gum oral supplement on the improvement of oxidant/ antioxidant and inflammatory indices, and Keap1/Nrf-2/ARE signaling pathway in patients with non-alcoholic fatty liver disease: A Randomized Clinical Trial

Public title

Investigating the effect of wild pistachio gum in the treatment of fatty liver disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having fatty liver grade 1 and 2 based on diagnosis by ultrasound Age 18-60 years Body mass index in the range of 25-35 kg/m2

Exclusion criteria:

The presence of secondary causes of hepatic steatosis (such as hepatitis B and C virus, autoimmune hepatitis, hemochromatosis, celiac disease, pituitary hypofunction, hypothyroidism, Wilson's disease, abetalipoproteinemia or corticosteroid drugs) Suffering from diseases such as Autoimmune, digestive, liver diseases (fibrosis, cirrhosis, (HCC, kidney, thyroid and cardiovascular diseases), severe respiratory disease (asthma and chronic bronchitis) Pregnancy Breastfeeding Alcohol consumption, consumption of plant sterols, psyllium and oil Fish, consumption of any kind of vitamins and minerals, nutritional supplements The existence of allergy to all kinds of Pistachio plant species

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

A random sequence will be generated by using the random block method using a random block of 4 for a total of 12 blocks that will be created using the website https://www.sealedenvelope.com.The person who collects the information is unaware of the type of allocation of the samples to the study groups. The following things will be considered regarding the implementation of the random assignment process: a) One English letter will be assigned to each of the groups: A to the supplement group, B to the placebo group. b) A sequence will be created for a sample size of 46 . c) For the concealment process of random allocation, 46 non-transparent envelopes and 46 cards (the size of the total sample size) will be prepared. Inside each envelope, 4 cards will be placed in the order of the sequence in each block. Block numbers will be written on each envelope. The name of the desired group will be written on each card in sequence. Due to the fact that people do not know about the random sequence and the considered blocks, random allocation concealment is observed and before the allocation of the individual, the allocated group will not be clear.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Except for an individual outside the study group who will number the randomization list and drug containers sequentially, all other investigators and all patients will be blinded to study group assignment. The placebo will be identical in shape and appearance to the supplement and will be distributed in similar containers.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Kermanshah University of Medical Sciences

Street address

Shahid Beheshti Blvd

City

Kermanshah

Province

Kermanshah

Postal code

6714673159

Approval date

2023-12-18, 1402/09/27

Ethics committee reference number

IR.KUMS.REC.1402.442

Health conditions studied

1

Description of health condition studied

Fatty liver

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description

Oxidative stress indicators (MDA, TAC, TOS)

Timepoint

Before and after study

Method of measurement

Calorimetric method

2

Description

Gene expression of antioxidant enzymes (NQO1, HMOX-1, GCLC)

Timepoint

Before and after study

Method of measurement

Real- Time PCR

3

Description

Nrf-2 gene expression

Timepoint

Before and after study

Method of measurement

Real- Time PCR

4

Description

Serum levels of inflammatory and anti-inflammatory factors (IL-10, IL-6)

Timepoint

Before and after study

Method of measurement

ELIZA method

Secondary outcomes

1

Description

Fasting insulin

Timepoint

Before and after study

Method of measurement

Calorimetric method

2

Description

fasting blood sugar

Timepoint

Before and after study

Method of measurement

Calorimetric method

3

Description

Insulin resistance index (HOMA-IR)

Timepoint

Before and after study

Method of measurement

Formula

4

Description

Insulin sensitivity index (QUICKI)

Timepoint

Before and after study

Method of measurement

Formula

5

Description

Function of pancreatic beta cells (HOMA-β)

Timepoint

Before and after study

Method of measurement

Formula

6

Description

Liver enzymes (AST, ALT)

Timepoint

Before and after study

Method of measurement

Calorimetric method

7

Description

Lipid profile (TC, HDL-C, TG, LDL-c)

Timepoint

Before and after study

Method of measurement

Enzymatic method

8

Description

The degree of hepatic steatosis

Timepoint

Before and after study

Method of measurement

sonography

Intervention groups

1

Description

Intervention group: Patients in the supplement group will take every 12 hours, 2 tablespoons of oral emulsion, each spoon containing 500 mg of Pistacia atlantica Sub Kurdica gum for 2 months. This emulsion will be produced by Barij Essential Pharmaceutical Company.

Category

Treatment - Other

2

Description

Control group: Patients in the placebo group will take 2 tablespoons of oral emulsion every 12 hours with the same appearance and composition as the gum supplement (but without Pistacia atlantica Sub. Kurdica gum) for 2 months. This emulsion will be produced by Barij Essential Pharmaceutical Company.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Bostan Specialized Medical Clinic
Full name of responsible person
Dr. Mohssen Fatahi Banvandpour
Street address
Sorkhe lizhe
City
Kermanshah
Province
Kermanshah
Postal code
6714673159
Phone
+98 83 3836 0014
Email
src_research@kums.ac.ir

2

Recruitment center

Name of recruitment center
Mehr clinic
Full name of responsible person
Dr. Mohamad Gharib Salehi
Street address
Haj Mohamad Taghi Esfahani
City
Kermanshah
Province
Kerman
Postal code
6714673159
Phone
+98 83 3836 0014
Email
src_research@kums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Dr. Siros Jalili
Street address
Shahid Beheshti Blvd
City
Kermanshah
Province
Kermanshah
Postal code
6714673159
Phone
+98 83 3836 0014
Email
src_research@kums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kermanshah 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
Kermanshah University of Medical Sciences
Full name of responsible person
Roghayeh Mostafaei
Position
PhD Student
Latest degree
Master
Other areas of specialty/work
Nutrition
Street address
Dolatabad
City
Kermanshah
Province
Kermanshah
Postal code
671987915
Phone

+98 83 3827 0803

Email

r_mostafai@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Seyed Mostafa Nachvak

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Dolatabad

City

Kermanshah

Province

Kermanshah

Postal code

6714673159

Phone

+98 83 3827 2001

Email

smnachvak@hotmail.com

Person responsible for updating data

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Roghayeh Mostafaei

Position

PhD Student

Latest degree

Master

Other areas of specialty/work

Nutrition

Street address

Dolatabad

City

Kermanshah

Province

Kermanshah

Postal code

671987915

Phone

+98 83 3827 0803

Email

r_mostafai@yahoo.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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

All information can be shared.

When the data will become available and for how long

6 months after the results are published

To whom data/document is available

Scientific referees of reputable journals

Under which criteria data/document could be used

Checking the accuracy of data by reviewer

From where data/document is obtainable

Email to corresponding author: Dr Seyed Mostafa Nachvak smnachvak@hotmail.com

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

Email The expected period is one month

Comments