Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jul 2026

The effect of propolis and placebo supplementation with weight loss diet on metabolic status, meta-inflammation, nutritional status and liver function in patients with non-alcoholic fatty liver

Protocol summary

Study aim

Determining the effect of propolis supplementation with weight loss diet on metabolic status, meta-inflammation, nutritional status and liver function in patients with non-alcoholic fatty liver: a randomized controlled clinical trial

Design

Clinical trial with control group, double-blind, randomized, phase 3 on 46 patients. Pass15 software was used for randomization.

Settings and conduct

Individuals randomly assigned to the supplement and placebo groups will take propolis or placebo supplements for 8 weeks. At the beginning of the study, both groups will be given a weight loss diet individually.

Participants/Inclusion and exclusion criteria

Inclusion criteria included patients with non-alcoholic fatty liver (grade 1 and 2) of both sexes, age 20-50 years, BMI between 30-40 kg/m2, willingness to participate in the study and exclusion criteria included Pregnancy, lactation and menopause in women, allergies to propolis or honey products, smoking and alcohol use, use of medications, supplements or diets that affect liver enzyme levels and body weight in the last three months and having symptoms of recent infectious or inflammatory disease or surgery.

Intervention groups

supplement group(three capsules containing 500 mg of propolis daily) placebo group(three capsules containing 500 mg of Corn starch) will receive for 8 weeks after each meal with weight loss diet.The amount of calories per person is calculated based on the Mifflin formula and 500 kcal will be deducted from the total calories.

Main outcome variables

FBS, Insulin, HOMA-IR, TC, TG, HDL-C, MCP-1, TNF-α, TLR-4, weight, height, BMI, WC,WHR, WHtR, Fatty liver grade, AST, ALT, GGT, NAFLD fibrosis score , Energy of macronutrients and micronutrients Received

General information

Reason for update

Acronym

NAFLD

IRCT registration information

IRCT registration number: **IRCT20100209003320N21**
Registration date: **2021-07-18, 1400/04/27**
Registration timing: **prospective**

Last update: **2021-07-18, 1400/04/27**
Update count: **0**

Registration date

2021-07-18, 1400/04/27

Registrant information

Name

Mehrangiz Ebrahimi mamagani

Name of organization / entity

Health & Nutrition faculty of Tabriz university of medical sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-23, 1400/05/01

Expected recruitment end date

2021-12-22, 1400/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of propolis and placebo supplementation with weight loss diet on metabolic status, meta-inflammation, nutritional status and liver function in patients with non-alcoholic fatty liver

Public title

The effect of propolis supplementation with weight loss diet in treatment of non-alcoholic fatty liver

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Both sexes Age 20-50 years Body mass index (BMI) in the range of 30-40 Kg/m2 Willingness to participate in the study Non-alcoholic fatty liver disease (NAFLD) (grades 1 and 2)

Exclusion criteria:

pregnancy, lactation and menopause in women Skin or gastrointestinal allergies to propolis, honey and any bee products Smoking or alcohol use Following a particular diet in the last three months Using synthetic or herbal medicines for weight loss in the last three months Performing weight loss surgery in the past year or strict weight loss diets in the last three months Use antibiotics or supplements affecting liver enzyme levels in the last three months Having symptoms of infectious or inflammatory disease or recent surgery

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **46**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, block randomization will be used to create a balance in the number of samples allocated to each of the study groups (supplement and placebo). All blocks will be the same size, and in this two-group experiment, there will be 6 blocks (including 3 participants in the supplement group and 3 participants in the placebo group). Randomization tool, RAS (Random allocation software) is version 2.0 that these random software in addition to simple randomization is also able to block randomization. Thus, 46 eligible patients will be blocked based on age, sex and BMI and will be randomly allocated to the supplement group (propolis) or placebo (cornstarch). Allocation concealment is also used for hiding so that the allocated group is not known before the individual is allocated.

Blinding (investigator's opinion)

Double blinded

Blinding description

The person in charge of packaging propolis and placebo supplements without knowing the content will determine the type of supplement or placebo that has no role in the implementation and analysis of the study data. None of the researchers or patients will be aware of the type of combination each person is receiving.

Placebo

Used

Assignment

Parallel

Other design features

Individuals in both the placebo and supplement groups will receive a weight loss diet; The amount of calories per person is calculated based on the Mifflin formula and 500 kcal will be deducted from the total calories in order to lose weight. The distribution of macronutrient calories will be 50% carbohydrates, 20% protein and 30% fat.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz university of medical sciences

Street address

Tabriz University of Medical Sciences, Attar Neishabouri Ave, Golgasht St

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Postal code

5166614711

Approval date

2021-02-16, 1399/11/28

Ethics committee reference number

IR.TBZMED.REC.1399.1059

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
Tumor necrosis factor
Timepoint
At the beginning and 8 weeks after the start of the study
Method of measurement
ELISA method

2

Description
MCP-1
Timepoint
At the beginning and 8 weeks after the start of the study
Method of measurement
ELISA method

3

Description
Toll-like receptor 4
Timepoint
At the beginning and 8 weeks after the start of the study
Method of measurement
ELISA method

4

Description
Fasting Blood Sugar
Timepoint
At the beginning and 8 weeks after the start of the study
Method of measurement
Enzymatic method

5

Description
Insulin
Timepoint
At the beginning and 8 weeks after the start of the study
Method of measurement
ELISA method

6

Description
Total cholesterol
Timepoint
At the beginning and 8 weeks after the start of the study
Method of measurement
Enzymatic method

7

Description
Triglyceride
Timepoint
At the beginning and 8 weeks after the start of the study
Method of measurement
Enzymatic method

8

Description
HDL-C
Timepoint
At the beginning and 8 weeks after the start of the study
Method of measurement
enzymatic colorimetric method using spectrophotometer

9

Description
HOMA-IR
Timepoint
At the beginning and 8 weeks after the start of the study
Method of measurement
According to the formula

10

Description
Body mass index
Timepoint
At the beginning and 8 weeks after the start of the study
Method of measurement
According to the formula

11

Description
waist circumference
Timepoint
At the beginning and 8 weeks after the start of the study
Method of measurement
Meter

12

Description
waist-to-hip ratio (WHR)
Timepoint
At the beginning and 8 weeks after the start of the study
Method of measurement
According to the formula

13

Description
Waist to Height Ratio (WHtR)
Timepoint
At the beginning and 8 weeks after the start of the study
Method of measurement
According to the formula

14

Description
Alanine aminotransferase
Timepoint
At the beginning and 8 weeks after the start of the study
Method of measurement
enzymatic method

15

Description
Aspartate aminotransferase
Timepoint
At the beginning and 8 weeks after the start of the study
Method of measurement
Enzymatic method

16

Description
Gamma Glutamyl transferase
Timepoint
At the beginning and 8 weeks after the start of the study
Method of measurement
Enzymatic method

17

Description
Fatty liver grade
Timepoint
At the beginning and 8 weeks after the start of the study
Method of measurement
Ultrasound findings

18

Description
NAFLD fibrosis score
Timepoint
At the beginning and 8 weeks after the start of the study
Method of measurement
According to the formula

19

Description
energy and macronutrients received
Timepoint
At the beginning and 8 weeks after the start of the study
Method of measurement
3-Day Food Record form

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Supplement group (propolis three capsules of 500 mg per day after each meal) for 8 weeks from Shahdineh Company of Isfahan with weight loss diet.The amount of calories for each person will be calculated based on the Mifflin formula and 500 kcal will be deducted from it in order to lose weight. The distribution of macronutrients will be 50% carbohydrates, 20% protein and 30% fat.
Category
Treatment - Drugs

2

Description
Control group: placebo (three capsules of 500 mg of corn starch per day after each meal) for 8 weeks from Shahdineh Company of Isfahan with weight loss diet.The amount of calories for each person will be calculated based on the Mifflin formula and 500 kcal will be deducted from it in order to lose weight. The distribution of macronutrients will be 50% carbohydrates, 20% protein and 30% fat.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
University of Nutrition and Food Science
Full name of responsible person
Dr. Mehrangiz Ebrahimi-Mameghani
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Sponsors / Funding sources

1

Sponsor
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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
Dr. Mehrangiz Ebrahimimamagani

Position
professor

Latest degree
Ph.D.

Other areas of specialty/work
Nutrition

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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
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
Yes - There is a plan to make this available

Title and more details about the data/document
Data collected for the primary outcomes will be shared

When the data will become available and for how long
Access starting 12 months after publication

To whom data/document is available
The data will only be available for people working in academic institutions.

Under which criteria data/document could be used

The data of the present study will only be accessible by other researchers , for conducting meta-analysis

From where data/document is obtainable

Ms.Mahlagha, Nikbaf, E-mail address:mahlaghanikbaf@gmail.com , cellphone number: 00989155122119

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

The applicant should provide a brief description of the aims and methods of his Meta-analysis . His request will be assessed and , if agreed, the data will be emailed to the applicant. All these procedures will take no longer than 15 days.

Comments