Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of propolis and placebo supplements associated with weight loss diet on prooxidant-antioxidant balance, oxidative stress status, nutritional status, liver function and body composition in patients with non-alcoholic fatty liver

Protocol summary

Study aim

The effect of propolis and placebo supplements associated with weight loss diet on prooxidant-antioxidant balance, oxidative stress status, nutritional status, liver function and body composition in patients with NAFLD

Design

Randomized double blind clinical trial with two arm parallel groups , phase 3 on 46 patients

Settings and conduct

Individuals randomly assigned to propolis and placebo groups. The duration of the study will be 8 weeks. Also, at the beginning of the study, both groups will be given individual weight loss diets.

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 including smoking and alcohol consumption, change in physical activity, pregnancy, lactation and menopause in women, skin or gastrointestinal allergies to propolis or bee products, having a weight loss diet 3 months before the study or recent surgery, taking any supplements or drugs that affect the condition and function of the liver and taking antioxidant supplements for 3 months before or during the study and also disease with similar pathogenesis

Intervention groups

The intervention group will receive a weight loss diet and propolis supplement (three capsules containing 500 mg of propolis per day) and the placebo group will receive a weight loss diet and placebo (three capsules containing 500 mg of corn starch per day) after each meal for 8 weeks.

Main outcome variables

Nutritional status (energy intake, macronutrients and antioxidant micronutrients), Pro-Oxidant-Antioxidant Balance, Oxidative status (total antioxidant capacity, glutathione peroxidase and superoxide dismutase and Malondialdehyde), Fat mass, Fat free mass, Body water, Fatty liver grade, Serum level of liver enzymes and liver fibrosis score

General information

Reason for update

Acronym

NAFLD

IRCT registration information

IRCT registration number: **IRCT20100209003320N20**
Registration date: **2021-06-27, 1400/04/06**
Registration timing: **prospective**

Last update: **2021-06-27, 1400/04/06**
Update count: **0**

Registration date

2021-06-27, 1400/04/06

Registrant information

Name

Mehrangiz Ebrahimi mamagani

Name of organization / entity

Health & Nutrition faculty of Tabriz university of medical sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2021-07-06, 1400/04/15
Expected recruitment end date
2021-12-16, 1400/09/25
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of propolis and placebo supplements associated with weight loss diet on prooxidant-antioxidant balance, oxidative stress status, nutritional status, liver function and body composition in patients with non-alcoholic fatty liver

Public title
The effect of propolis supplementation in treatment of non-alcoholic fatty liver
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
NAFLD (Grade 1 and 2) Age 20-50 years Body mass index(BMI) in the range of 30-40 Kg / m2 Willingness to participate in the study
Exclusion criteria:
Pregnancy, lactation and menopause in women Smoking and alcohol use Skin or gastrointestinal allergies to propolis, honey and any of the beehive products Adherence to a special diet three months before the study Consumption of chemical or herbal medicines for weight loss Taking antibiotics or various supplements that affect the levels of liver enzymes Performing weight loss surgery in the last year or strict weight loss diets in the last three months Suffering from any conditions affecting liver function Use of hepatotoxic medications Taking multivitamins or antioxidant supplements during the last 3 months
Age
From **20 years** old to **50 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **46**
Randomization (investigator's opinion)
Randomized
Randomization description
46 eligible patients will be randomly allocated to intervention and placebo groups using a software generated random permuted blocks. The generated random sequence will be kept in a protected location and administered by an independent third party who is blind to the trial throughout the study
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, the main investigators ((including the student and her supervisors and adviser professors as well as the patients) will be blinded to the type of the supplement (propolis or placebo) received by each patient
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
Attar Nishapuri Street , Faculty of Nutrition and Food Science
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tabriz
Province
East Azarbaijan
Postal code
5166614711
Approval date
2021-01-11, 1399/10/22
Ethics committee reference number
IR.TBZMED.REC.1399.942

Health conditions studied

1

Description of health condition studied
Non-alcoholic fatty live
ICD-10 code
K76.0
ICD-10 code description
Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description
Pro-Oxidant Antioxidant Balance (PAB)
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Enzymatic_ colorimetric method and read it through ELISA

2

Description
Glutathione peroxidase(GPX)
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Spectrophotometric method

3

Description
Superoxide dismutase (SOD)
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Spectrophotometric method

4

Description
Malondialdehyde (MDA)
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Spectrophotometric method

5

Description
Total Antioxidant Capacity (TAC)
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Spectrophotometric method

6

Description
Fat mass
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Using bioelectric impedance analyzer

7

Description
Free fat mass
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Using bioelectric impedance analyzer

8

Description
Body water
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Using bioelectric impedance analyzer

9

Description
Intake of energy, macronutrients and antioxidant micronutrients
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
The intake by 3-days food record form and analysis using nutritionist 4 software

10

Description
Alanine aminotransferase
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Enzymatic method

11

Description
Aspartate aminotransferase
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Enzymatic method

12

Description
Gamma Glutamyl transferase
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Enzymatic method

13

Description
Fatty liver grade
Timepoint
Baseline and 8 weeks after intervention
Method of measurement
Ultrasound findings

14

Description
Liver fibrosis score
Timepoint

Baseline and 8 weeks after intervention

Method of measurement

Liver fibrosis score formula

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients in this group will receive a weight loss diet with propolis supplement (3 capsules of 500 mg per day) after each meal for 8 weeks. This supplement is provided by Shahdineh Company of Isfahan.

Category

Treatment - Drugs

2

Description

Control group: Patients in this group will receive a weight loss diet with placebo supplement (3 500 mg capsules per day of cornstarch) for 8 weeks after each meal. This supplement is provided by Shahdineh Company of Isfahan.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Sheikh Al-Rais Clinic

Full name of responsible person

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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?

No

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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Position
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Person responsible for updating data

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Full name of responsible person
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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.Hamideh, Nazari bonab, E-mail address:hamideh.nazarii@gmail.com, cellphone number: 00989148616822

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