Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Oct 2026

Effect of Propolis on liver functional indexes in patients with Non-alcoholic fatty liver disease

Protocol summary

Study aim
Effect of Propolis on liver functional indexes in patients with non-alcoholic fatty liver disease

Design
A concealed, randomized, blinded, sham controlled clinical trial with a parallel group design of 501 patients,

Settings and conduct
In a double-blind randomized clinical trial, 50 patients with NAFLD who were referred to the gastroenterology clinic of Tohid Hospital in Sanandaj were divided in two groups and treated with Propolis capsules (2 capsules 500 mg, daily) or placebo for 3 months. All subjects receive two groups of dietary and physical activity recommendations during the study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: subjects over 20 years old who were diagnosed with NAFLD by Sonography and increased levels of ALT and AST Exclusion criteria:viral hepatitis; autoimmune liver diseases; diabetes; women who were pregnant or lactating; Use of effective drugs on liver tests in the last 2 months (Statins, Glitazones , Chlorpromazine , Vit E, OCP , Anabolic Steroids, Thionamides , etc.) ; Hemochromatosis ; Cirrhosis ; Alcohol consumption of more than 140cc in men and 70 cc in women per week ; Infectious diseases; herbal allergies, history of allergic reactions to bee products

Intervention groups
Intervention group: Propolis, oral capsule, 500 mg, twice a day for three months with standard treatment Control group: placebo containing starch, oral capsule, 500 mg, twice a day for three months with standard treatment

Main outcome variables
Alanine Aminotransferase (ALT); Aspartate Aminotransferase (AST); Alkaline Phosphatase (ALP); Gamma glutamyl transpeptidase; Albumin; Ferritin; Bilirubin; Cholestrol; Triglyceride; High Density Lipoprotein (HDL); Low Density Lipoprotein (LDL); Grade of fatty liver; En Body Mass Index (BMI)

General information

Reason for update

Acronym
NAFLD

IRCT registration information
IRCT registration number: **IRCT20161023030445N2**
Registration date: **2018-03-26, 1397/01/06**
Registration timing: **registered_while_recruiting**

Last update: **2018-03-26, 1397/01/06**
Update count: **0**

Registration date
2018-03-26, 1397/01/06

Registrant information

Name
Vahid Yousefinejad
Name of organization / entity
Kurdistan University of Medical Sciences
Country
Iran (Islamic Republic of)
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-12-22, 1396/10/01

Expected recruitment end date
2018-12-22, 1397/10/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of Propolis on liver functional indexes in patients with Non-alcoholic fatty liver disease

Public title
Effect of Propolis on Non-alcoholic fatty liver disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
subjects over 20 years old subjects diagnosed with NAFLD by increased levels of ALT and AST Confirmation of NAFLD in Sonography report
Exclusion criteria:
viral hepatitis or autoimmune diabetes women who were pregnant or lactating Use of effective drugs on liver tests in the last 2 months (Statins, Glitazones , Chlorpromazine , Vit E, OCP , Anabolic Steroids, Thionamides , etc.) Hemochromatosis Cirrhosis Alcohol consumption of more than 140cc in men and 70 cc in women per week Infectious diseases herbal allergies history of allergic reactions to bee products.
Age
From **20 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
using block randomization method with a block size of 4. The list of randomization was computer-generated and a person, who was not aware of the nature of the trial, packed the supplements and placebo capsules in numbered bottles based on the list. The other person who was not aware of random sequences allocated the patients to the numbered bottles.
Blinding (investigator's opinion)
Double blinded
Blinding description
All supplements and placebo capsules were identical with respect to appearance and only differed in coding of the capsules. The treatment code of the intervention supplements was blinded for subjects, investigators and staff involved in the conduct of the study.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Kurdistan university of medical sciences
Street address
Vice Chancellor for research of Kurdistan University of Medical Sciences, Pasdaran Blvd, Sanandaj, Iran.
City
Sanandaj
Province
Kurdistan
Postal code
66177-13446
Approval date
2016-10-31, 1395/08/10
Ethics committee reference number
MUK.REC.1395.198

Health conditions studied

1

Description of health condition studied
Nonalcoholic fatty liver disease (NAFLD)
ICD-10 code
K76.0
ICD-10 code description
Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description
Alanine Aminotransferase (ALT)
Timepoint
in the beginning and end of Intervention
Method of measurement
mg/dl by using specific serum kit

2

Description
Aspartate Aminotransferase (AST)
Timepoint
in the beginning and end of Intervention
Method of measurement
mg/dl by using specific serum kit

3

Description
Grade of fatty liver
Timepoint
in the beginning and end of Intervention
Method of measurement
Sonography

4

Description
Alkaline Phosphatase (ALP)
Timepoint
in the beginning and end of Intervention
Method of measurement
mg/dl by using specific serum kit

5

Description
Body Mass Index (BMI)
Timepoint
in the beginning and end of Intervention
Method of measurement
kg/m2 by measuring height and weight and use of scale

6

Description
Gamma glutamyl transpeptidase
Timepoint
in the beginning and end of Intervention
Method of measurement
mg/dl by using specific serum kit

7

Description
Albumin
Timepoint
in the beginning and end of Intervention
Method of measurement
mg/dl by using specific serum kit

8

Description
Ferritin
Timepoint
in the beginning and end of Intervention
Method of measurement
mg/dl by using specific serum kit

9

Description
Bilirubin
Timepoint
in the beginning and end of Intervention
Method of measurement
mg/dl by using specific serum kit

10

Description
Cholestrol
Timepoint
in the beginning and end of Intervention
Method of measurement
mg/dl by using specific serum kit

11

Description
Triglyceride
Timepoint
in the beginning and end of Intervention
Method of measurement
mg/dl by using specific serum kit

12

Description
High Density Lipoprotein (HDL)
Timepoint
in the beginning and end of Intervention
Method of measurement
mg/dl by using specific serum kit

13

Description
Low Density Lipoprotein (LDL)
Timepoint
in the beginning and end of Intervention
Method of measurement
mg/dl by using specific serum kit

Secondary outcomes

1

Description
Fasting Blood Serum
Timepoint
in the beginning and end of Intervention
Method of measurement
mg/dl by using specific serum kit

2

Description
TNFα
Timepoint
in the beginning and end of Intervention
Method of measurement
Pg/ml by using specific serum kit

3

Description
Interleukin 6
Timepoint
in the beginning and end of Intervention
Method of measurement
Pg/ml by using specific serum kit

Intervention groups

1

Description
Control group: placebo containing starch, oral capsule, 500 mg, twice a day for three months with standard

treatment

Category

Placebo

2

Description

Intervention group: Propolis, oral capsule, 500 mg, twice a day for three months with standard treatment

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Gastroenterology Clinic of Tohid Hospital

Full name of responsible person

Dr. Vahid Yousefinejad

Street address

Tohid Hospital, Geriashan Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Kurdistan University of Medical Sciences

Full name of responsible person

Dr.Rasoul Nasiri

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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

Vice Chancellor for research of Kurdistan 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

Liver & Digestive Research Center,Kurdistan university of medical sciences

Full name of responsible person

Dr. Vahid Yousefinejad

Position

Faculty Member

Latest degree

Specialist

Other areas of specialty/work

Forensic Medicine

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Liver & Digestive Research center,Kurdistan university of medical sciences

Full name of responsible person

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Position

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Latest degree

Specialist

Other areas of specialty/work

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Position
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Latest degree
Specialist
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be 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