

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 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; Cholesterol; 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)

##### Phone

+98 87 3366 0089

##### Email address

dr.v.yousefinejad@muk.ac.ir

##### 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/m<sup>2</sup> 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**

Cholesterol

### **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**

TNF $\alpha$

#### **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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Sanandaj

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6616812131

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hooman56y@yahoo.com

**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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Vice Chancellor for research of Kurdistan University of Medical Sciences, Pasdaran Blvd, Sanandaj, Iran.

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Rasool\_nsr@yahoo.com

**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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Hospital Research Department,Tohid Hospital, Geriashan Ave Sanandaj

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**Person responsible for scientific inquiries**

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**Full name of responsible person**

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**Latest degree**

Specialist

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

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**Full name of responsible person**  
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**Position**  
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**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Forensic Medicine  
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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