

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### Effect of Propolis extract on hepatic steatosis and fibrosis status in patients with non-alcoholic fatty liver disease

#### Protocol summary

##### Study aim

The main aim of this randomized clinical trial is to evaluate the protective potential of Propolis extract on hepatic and fibrosis and steatosis among non-alcoholic fatty liver disease patients with the diagnosis of hepatic fibrosis.

##### Design

The current study will be a 4- month intervention with Propolis extract among non-alcoholic fatty liver disease patients with hepatic elastography-diagnosed hepatic fibrosis. The written informed consent will be obtained from patients who will participate in the study at enrollment time. Participants will be assessed for eligibility criteria in the first visit. The randomization procedure will be performed using the stratified block method. Eligible participants will randomly be assigned to one of two groups; a group received Propolis extract at a dose of 500 mg per day and a group received placebo. With the exception of Pharmacist, the treatment assignment will be concealed from the patients, care provider, investigator, outcome assessor and data analyser, and data and safety monitoring board throughout the study.

##### Settings and conduct

Participants will be recruited from outpatients attending gastroenterology clinic at Imam Reza hospital in Mashhad, Iran.

##### Participants/Inclusion and exclusion criteria

non-alcoholic fatty liver disease patients with the diagnosis of hepatic fibrosis

##### Intervention groups

Intervention group: Propolis extract at a dose of 500 mg per day for four consecutive months  
Control group: Placebo at a dose of 500 mg per day for four consecutive months

##### Main outcome variables

Hepatic steatosis and fibrosis

#### General information

##### Reason for update

Information correction

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180824040857N1**

Registration date: **2018-10-24, 1397/08/02**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-09-19, 1399/06/29**

Update count: **1**

##### Registration date

2018-10-24, 1397/08/02

##### Registrant information

##### Name

Davoud Soleimani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 3800 2423

##### Email address

DAVOUD.SOLEIMANI@kums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-08-01, 1397/05/10

##### Expected recruitment end date

2018-10-26, 1397/08/04

##### Actual recruitment start date

2018-08-01, 1397/05/10

##### Actual recruitment end date

2018-10-26, 1397/08/04

##### Trial completion date

2019-02-28, 1397/12/09

## Scientific title

Effect of Propolis extract on hepatic steatosis and fibrosis status in patients with non-alcoholic fatty liver disease

## Public title

Effect of Propolis extract on non-alcoholic fatty liver disease

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Having evidence of fibrosis and steatosis on liver elastography  
The absence of alcohol consumption  
Having no secondary causes of hepatic steatosis such as hepatitis C virus, autoimmune hepatitis, haemochromatosis, hypopituitarism, hypothyroidism, Wilson's disease, and regular use of hepatotoxic drugs (e.g., amiodarone, tamoxifen, valproate, methotrexate) or corticosteroids.

### Exclusion criteria:

Pregnancy  
Lactation  
Having weight management program

## Age

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

## Gender

Both

## Phase

2

## Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

## Sample size

Target sample size: **54**

Actual sample size reached: **54**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Stratified block randomization

## Blinding (investigator's opinion)

Triple blinded

## Blinding description

With the exception of a pharmacist, the treatment assignment will be concealed from the patients, care provider, investigator, outcome assessor, data analyser, and data and safety monitoring board throughout the study.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

##### Street address

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9177948564

#### Approval date

2018-07-09, 1397/04/18

#### Ethics committee reference number

IR.MUMS.MEDICAL.REC.1397.121

## Health conditions studied

### 1

#### Description of health condition studied

Non- alcoholic fatty liver disease (NAFLD)

#### ICD-10 code

K76.0

#### ICD-10 code description

Fatty (change of) liver, not elsewhere classified

## Primary outcomes

### 1

#### Description

Hepatic steatosis

#### Timepoint

At the beginning of the study and the fourth month of the intervention

#### Method of measurement

Two-dimensional shear wave elastography (2-D SWE)

### 2

#### Description

Hepatic fibrosis

#### Timepoint

At the beginning of the study and the fourth month of the intervention

#### Method of measurement

Two-dimensional shear wave elastography (2-D SWE)

## Secondary outcomes

### 1

#### Description

Alanine aminotransferase (ALT)

**Timepoint**

At the beginning of the study and the fourth month of the intervention

**Method of measurement**

Colorimetric assay with the use of commercial kits(Pars Azmoon, Tehran, Iran)

**2**

**Description**

Aspartate aminotransferase (AST)

**Timepoint**

At the beginning of the study and the fourth month of the intervention

**Method of measurement**

Colorimetric assay with the use of commercial kits(Pars Azmoon, Tehran, Iran)

**3**

**Description**

Total cholesterol

**Timepoint**

At the beginning of the study and the fourth month of the intervention

**Method of measurement**

Colorimetric assay with the use of commercial kits(Pars Azmoon, Tehran, Iran)

**4**

**Description**

LDL

**Timepoint**

At the beginning of the study and the fourth month of the intervention

**Method of measurement**

Colorimetric assay with the use of commercial kits(Pars Azmoon, Tehran, Iran)

**5**

**Description**

HDL

**Timepoint**

At the beginning of the study and the fourth month of the intervention

**Method of measurement**

Colorimetric assay with the use of commercial kits(Pars Azmoon, Tehran, Iran)

**6**

**Description**

TG

**Timepoint**

At the beginning of the study and the fourth month of the intervention

**Method of measurement**

Colorimetric assay with the use of commercial kits(Pars Azmoon, Tehran, Iran)

**7**

**Description**

fasting blood sugar (FBS)

**Timepoint**

At the beginning of the study and the fourth month of the intervention

**Method of measurement**

Colorimetric assay with the use of commercial kits(Pars Azmoon, Tehran, Iran)

**Intervention groups**

**1**

**Description**

Intervention group: Propolis extract at a dose of 500 mg per day for four consecutive months

**Category**

Treatment - Drugs

**2**

**Description**

Control group:Placebo at a dose of 500 mg per day for four consecutive months

**Category**

Placebo

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Gastroenterology clinic at Imam Reza hospital

**Full name of responsible person**

Dr. Ladan Goshadi

**Street address**

Imam Reza Hospital, Ibn Sina Avenue, Imam Reza Square

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9137913316

**Phone**

+98 51 3854 3031

**Fax**

**Email**

GoshayeshiL@mums.ac.ir

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr. Mohsen Tafaghodi

**Street address**

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

91775-1365

**Phone**

+98 51 1882 3255

**Fax**

+98 51 1882 3251

**Email**

tafaghodim@mums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Mashhad 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**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr. Mohsen Nematy

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Nutrition

**Street address**

Faculty of Medicine, Mashhad University of Medical Sciences, Paradise Daneshgah, Azadi Square

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

91779-48564

**Phone**

+98 51 3882 7033

**Fax**

+98 51 3800 2421

**Email**

NematyM@mums.ac.ir

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Dr. Mohsen Nematy

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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+98 51 3882 7033

**Fax**

+98 51 3800 2421

**Email**

NematyM@mums.ac.ir

**Person responsible for updating data****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Davoud Soleimani

**Position**

Ph D. candidate

**Latest degree**

Master

**Other areas of specialty/work**

Nutrition

**Street address**

Faculty of Medicine, Mashhad University of Medical Sciences, Paradise Daneshgah, Azadi Square

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

91779-48564

**Phone**

+98 915 064 1982

**Email**

Soleimanind941@mums.ac.ir

**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**

No - There is not a plan to make this available

**Clinical Study Report**

Yes - There is a plan to make this available

**Analytic Code**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

The non-identifiable individual participant data collected in this study will be shared. Also, The protocol, results, and statistical analysis of the current study will be published in the relevant articles.

**When the data will become available and for how long**

The non-identifiable individual participant data will become available after the publication of the relevant articles.

**To whom data/document is available**

The non-identifiable individual participant data will become available to other researchers in academic institutions.

**Under which criteria data/document could be used**

The non-identifiable individual participant data can only be used for research.

**From where data/document is obtainable**

The non-identifiable individual participant data will be obtainable by sending an e-mail to Dr. Mohsen Nematy. ( e-mail address: NematyM@mums.ac.ir)

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

Other researchers in academic institutions can send their request by e-mail to Dr. Mohsen Nematy. The data will be sent to them after consulting and approving the research team.

**Comments**