

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen Tafaghodi

Street address

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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

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

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

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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

Nutrition

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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

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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

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