Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Nov 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

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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 updating data

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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