Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Evaluation of the efficacy of Noushin-Shahd-herbal-syrup on markers of liver function, inflammation and oxidative stress in patients with non-alcoholic fatty liver disease; a double blind randomized clinical trial study

Protocol summary

Study aim

The effect of herbal syrup on markers of liver function, inflammation and oxidative stress in patients with non-alcoholic fatty liver disease

Design

This study is a double-blind and parallel clinical trial that will be conducted in two groups of 30 people on patients with non-alcoholic fatty liver disease referred to hepatologists and gastroenterologists.

Settings and conduct

Patients with non-alcoholic fatty liver disease referred to gastroenterology and liver specialists in Kerman city will randomly receive herbal syrup or placebo in two groups of 30 people in a double-blind manner.

Participants/Inclusion and exclusion criteria

Inclusion criteria Age between 30 and 65 years, Consistency of exercise program, Body mass index less than 40, Not having a specific disease, and Not drinking alcohol Exclusion criteria Performing CABG surgery, the occurrence of ASC, heart and brain stroke, pulmonary embolism, deep vein thrombosis, or TIA in the last 1 year Taking anti-inflammatory drugs such as aspirin with an anti-inflammatory dose, antioxidant supplements, vitamins and omega-3 capsules (<1 g/day), and immunosuppressive drugs in the last three months Presence of cancer, liver, and thyroid diseases pregnancy alcohol consumption Taking drugs that lower blood cholesterol and triglycerides

Intervention groups

The intervention group will drink herbal syrup and the control group will drink placebo.

Main outcome variables

The amount of liver enzymes (ALT, AST and ALP), Oxidative stress parameters (MDA, PC, TAC, TOC), the amount of inflammation parameters (hsCRP, IL-6 and TNF-a)

General information

Reason for update

Acronym

Noshin NAFLD

IRCT registration information

IRCT registration number: **IRCT20221216056833N1**
Registration date: **2023-02-15, 1401/11/26**
Registration timing: **prospective**

Last update: **2023-02-15, 1401/11/26**
Update count: **0**

Registration date

2023-02-15, 1401/11/26

Registrant information

Name

Hossein Pourghadamyari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3132 5829

Email address

ghadamyarih91@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-04-21, 1402/02/01

Expected recruitment end date

2023-08-23, 1402/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of the efficacy of Noushin-Shahd-herbal-syrup on markers of liver function, inflammation and oxidative stress in patients with non-alcoholic fatty liver disease; a double blind randomized clinical trial study

Public title
The effect of Noshin Shahd herbal syrup on liver function of patients with alcoholic fatty liver disease

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age between 30 and 65 years Consistency of exercise program Body mass index less than 40 Not having a specific disease Not drinking alcohol

Exclusion criteria:
Performing CABG surgery, occurrence of ASC, heart and brain stroke, pulmonary embolism, deep vein thrombosis or TIA in the last 1 year Taking anti-inflammatory drugs such as aspirin with an anti-inflammatory dose, antioxidant supplements, vitamins and omega-3 capsules (<1 g/day), and immunosuppressive drugs in the last three months Presence of cancer, liver and thyroid diseases pregnancy alcohol consumption Taking drugs that lower blood cholesterol and triglycerides

Age
From **30 years** old to **65 years** old

Gender
Both

Phase
4

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization process will be according to the stratified randomization method. Stratification of patients will be performed based on age, gender, and BMI, With the help of Winpepi software (V 11.6).

Blinding (investigator's opinion)
Double blinded

Blinding description
The patient receives the drug or placebo in sealed envelopes that are coded. Coding is done by one of the colleagues of the project and the medicine, evaluator, and patient will be blinded.

Placebo
Used

Assignment
Parallel

Other design features
It reminds us that the extract of ten plants effective in the treatment of fatty liver disease, produced by Nursing Shahdarumieh company, is mass produced with health license number 12.14310 since 2018. This product contains the effective ingredients of common safe medicinal plants that are effective in the treatment of fatty liver disease. It should be noted that during the 4 years of providing the product to the applicants, while declaring the satisfaction of the customers with the performance of the product, no toxicity or complaints have been reported from the people consuming the extract of ten plants.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kerman University of Medical Sciences

Street address
Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran

City
Kerman

Province
Kerman

Postal code
7616913555

Approval date
2023-02-06, 1401/11/17

Ethics committee reference number
IR.KMU.REC.1401.496

Health conditions studied

1

Description of health condition studied
Non-alcoholic fatty liver disease

ICD-10 code
K76.0

ICD-10 code description
Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description
liver steatosis level

Timepoint
Before the intervention and 40 days after the intervention

Method of measurement
Fibroscan

Secondary outcomes

1

Description
Serum levels of ALT
Timepoint
Before the intervention and 40 days after the intervention
Method of measurement
Biochemical Autoanalyzor

Intervention groups

1

Description
All the volunteers who meet the entry criteria were directed to the laboratory and imaging center so that biochemical tests and liver fibroscans can be performed on them before taking the drug. Volunteers are asked to take the received medicine twice a day after food. It is worth mentioning that the patients will be divided into two groups by a person outside the research team, one group will drink herbal syrup and the other group will receive a placebo. A placebo with the same appearance as herbal syrup will drink nectar. On a weekly basis, the researcher will make phone calls with the applicants and, while reminding and recording the amount of herbal syrup consumed by drinking nectar, will also ask about the possible side effects of consuming herbal syrup drinking nectar. Then, at the end of the eighth week, the patient was asked to visit the clinic for a final evaluation. In this stage, the patient is asked about possible side effects, and the last stage of sample collection will be done to review all the tests of the next stage of receiving the drug (biochemical tests and liver fibroscan). Return at the end of week 8.
Category
Treatment - Drugs

2

Description
It is worth mentioning that the placebo with the same appearance as the herbal syrup will be drinking nectar. On a weekly basis, the researcher can contact the applicants by phone and while reminding them to use the placebo, they will also be informed about the possible side effects of its use. Biochemical tests and liver fibroscans will be performed on them before taking the placebo. The volunteers were asked to take the received placebo twice a day after meals. Then, at the end of the eighth week, the patient was asked to visit the clinic for a final evaluation. At this stage, the patient will be asked about possible side effects, and the last stage of sample collection will be done to review all the tests for the next stage of receiving theplacebo (biochemical tests and liver fibroscan).
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Herbal and traditional medicines Research Center
Full name of responsible person
Hossein Pourghadamyari
Street address
Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran
City
Kerman
Province
Kerman
Postal code
7616913555
Phone
+98 34 3325 7448
Fax
+98 34 3325 7448
Email
ghadamyarih91@gmail.com
Web page address
https://htmrc.kmu.ac.ir/en

2

Recruitment center
Name of recruitment center
Gastroenterology and Hepatology Research Center
Full name of responsible person
Omid Eslami
Street address
Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran
City
Kerman
Province
Kerman
Postal code
7616913555
Phone
+98 34 3325 7470
Fax
+98 34 3325 7470
Email
sarashafieipour@yahoo.com
Web page address
https://ghrc.kmu.ac.ir/en

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Hossein Pourghadamyari
Street address

Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran

City
Kerman

Province
Kerman

Postal code
7616913555

Phone
+98 34 3132 5829

Fax
+98 34 3132 5830

Email
ghadamyarih91@gmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Kerman University of Medical Sciences

Proportion provided by this source
50

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
Kerman University of Medical Sciences

Full name of responsible person
Hossein Pourghadamyari

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Biochemistry

Street address
Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran

City
Kerman

Province
Kerman

Postal code
7616913555

Phone
+98 34 3325 7448

Fax
+98 34 3325 7448

Email
ghadamyarih91@gmail.com

Web page address
https://isid.research.ac.ir/Hossein_Pourghadamyari

Person responsible for scientific inquiries

Contact

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Hossein Pourghadamyari

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Biochemistry

Street address
Kerman University of Medical Sciences, Medical University Campus,Haft-Bagh Highway, Kerman, Iran

City
Kerman

Province
Kerman

Postal code
7616913555

Phone
+98 34 3325 7448

Fax
+98 34 3325 7448

Email
ghadamyarih91@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Kerman University of Medical Sciences

Full name of responsible person
Hossein Pourghadamyari

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Biochemistry

Street address
Kerman University of Medical Sciences, Medical University Campus, Haft-Bagh Highway, Kerman, Iran

City
Kerman

Province
Kerman

Postal code
7616913555

Phone
+98 34 3325 7448

Fax
+98 34 3325 7448

Email
ghadamyarih91@gmail.com

Web page address
https://isid.research.ac.ir/Hossein_Pourghadamyari

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
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is 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
Not applicable

Title and more details about the data/document
A part of the data such as the information related to the main outcome or the like can be shared.

When the data will become available and for how long
Access to study documentation after results are published

To whom data/document is available
It will be available for researchers working in academic and scientific institutions, and also people who are working in the industry can apply for them.

Under which criteria data/document could be used
For secondary studies

From where data/document is obtainable
The herbal and traditional medicines Research Center of Kerman University of Medical Sciences.

What processes are involved for a request to access data/document
The request sent will be reviewed by the members of the center. If the members agree, they will be notified.

Comments
There is no further information.