

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### Evaluation of the efficacy of Noshin-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 Autoanalyzer

## 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 the placebo (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](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](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.