

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 2026

### The effect of hydro-alcoholic extract of *Portulaca Oleracea* L. (purslane) on Liver enzymes, Glycemic status and lipid profile in non-alcoholic fatty liver disease: a randomized, double-blind clinical trial.

#### Protocol summary

##### Study aim

The aim of this study was to evaluate the effect of portulaca oleracea (purslane) hydroalcoholic extract in patients with non-alcoholic fatty liver disease (NAFLD).

##### Design

A 12-week randomized, double-blinded, parallel clinical trial on 74 patients with NAFLD.

##### Settings and conduct

Patients are randomly divided into intervention and placebo groups (37 patients in each group). The study process is described for each patient and a written consent form is obtained from the patients. The degree of hepatic steatosis is determined using ultrasound once at the beginning and again at week 12 of the study. The 3-day of 24-hour dietary recall is taken at the beginning and end of the study. A diet for 10% weight loss will be provided to each patients individually by a nutritionist. Patients' compliance is monitored by telephone every 15 days. Fasting blood samples are taken from patients at the beginning and at end of the study. The study protocol has been approved by the ethics committee of Iran University of Medical Sciences.

##### Participants/Inclusion and exclusion criteria

Men and women with non-alcoholic fatty liver disease whose ALT is greater than 30 U / l and more than 19 U / L, respectively, and who do not have chronic liver disease, cardiovascular disease, hypertension, or kidney stones are eligible to participate in the study.

##### Intervention groups

Intervention group: one capsule containing 300 mg of purslane hydroalcoholic extract daily. Placebo Group: A capsule daily similar in appearance to drug capsules, filled with toasted powder.

##### Main outcome variables

Serum levels of ALT and AST are the main outcomes of the study. Other variables include fasting blood glucose, insulin, total cholesterol, triglycerides, HDL-C, LDL-C,

gamma glutamyl transferase, alkaline phosphatase, glutathione peroxidase, total bilirubin, adiponectin, NF-κB and expression of the NF-κB gene.

#### General information

##### Reason for update

1. Submission of information in the old version of IRCT 2. Creating some changes in the sample size after the approval of the Vice Chancellor for Research of Iran University of Medical Sciences 3. Correcting the secondary outcome variables

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201701172709N44**  
Registration date: **2017-04-10, 1396/01/21**  
Registration timing: **prospective**

Last update: **2020-06-21, 1399/04/01**

Update count: **2**

##### Registration date

2017-04-10, 1396/01/21

##### Registrant information

###### Name

Farzad Shidfar

###### Name of organization / entity

Iran University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8862 2755

###### Email address

shidfar.f@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice Chancellor for Research of Iran university of Medical

Sciences

**Expected recruitment start date**

2017-06-22, 1396/04/01

**Expected recruitment end date**

2018-06-22, 1397/04/01

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The effect of hydro-alcoholic extract of Portulaca Oleracea L. (purslane) on Liver enzymes, Glycemic status and lipid profile in non-alcoholic fatty liver disease: a randomized, double-blind clinical trial.

**Public title**

Effect of purslane extract on non-alcoholic fatty liver disease

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Being volunteer or Wishing to attend Age 18 years or older Alanine aminotransferase (ALT) greater than 19 IU/L for women and greater than 30 IU/L for men Evidence of fatty liver in ultrasonography with a score of 1 or more BMI: 20-40 kg/m<sup>2</sup>

**Exclusion criteria:**

Other acute or chronic hepatic disorders (hepatitis B or C) Biliary diseases Cancer Hypertension History of cardiovascular disease Nephrolithiasis (oxalate stones) or history of oxalate stones Consumption of omega-3 and vitamin E supplement Alcohol use Use of hepatotoxic medications during last month Changing medication dosage during the study Pregnancy Lactation Compliacne less than 80%

**Age**

From **18 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator

**Sample size**

Target sample size: **74**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Block randomization method has been used for randomization. Blocks of size 4 are generated using www.sealedenvelope.com. In order to conceal in the randomization process, unique codes have been used on the medicine boxes, which are produced by the software.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

In order to apply concealment in the randomization process, unique codes will be used on the medicine boxes, and the desired code will also be produced by the software.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics Committee of Iran University of Medical Sciences

**Street address**

Iran University of Medical Sciences, Shahid Hemmat Highway.

**City**

Tehran

**Province**

Tehran

**Postal code**

1449614535

**Approval date**

2017-02-22, 1395/12/04

**Ethics committee reference number**

IR.IUMS.REC 1395.95-04-27-9221324202

**Health conditions studied****1****Description of health condition studied**

Nonalcoholic fatty liver disease

**ICD-10 code**

K76.0

**ICD-10 code description**

Fatty (change of) liver, not elsewhere classified

**Primary outcomes****1****Description**

Alanine aminotransferase (ALT)

**Timepoint**

At the begining and at the end of week 12

**Method of measurement**

Laboratory kit

**2****Description**

Aspartate aminotransferase (AST)

**Timepoint**

At the beginning and at the end of week 12

**Method of measurement**

Laboratory kit

**Secondary outcomes**

**1**

**Description**

Weight

**Timepoint**

At the beginning and at the end of week 12

**Method of measurement**

Seca scale

**2**

**Description**

Body mass index (BMI)

**Timepoint**

At the beginning and at the end of week 12

**Method of measurement**

Calculation: weight (in kilograms) divided by the square of height (in meters)

**3**

**Description**

Waist circumference

**Timepoint**

At the beginning and at the end of week 12

**Method of measurement**

Non-stretchable measuring tape

**4**

**Description**

Liver steatosis

**Timepoint**

At the beginning and at the end of week 12

**Method of measurement**

Sonography

**5**

**Description**

Systolic blood pressure (SBP)

**Timepoint**

At the beginning and at the end of week 12

**Method of measurement**

Sphygmomanometer

**6**

**Description**

Diastolic blood pressure (DBP)

**Timepoint**

At the beginning and at the end of week 12

**Method of measurement**

Sphygmomanometer

**7**

**Description**

Total cholesterol

**Timepoint**

At the beginning and at the end of week 12

**Method of measurement**

Laboratory kit

**8**

**Description**

Triglyceride (TG)

**Timepoint**

At the beginning and at the end of week 12

**Method of measurement**

Laboratory kit

**9**

**Description**

High density lipoprotein (HDL)

**Timepoint**

At the beginning and at the end of week 12

**Method of measurement**

Laboratory kit

**10**

**Description**

Low density lipoprotein (LDL)

**Timepoint**

At the beginning and at the end of week 12

**Method of measurement**

Laboratory kit

**11**

**Description**

Albumin (ALB)

**Timepoint**

At the beginning and at the end of week 12

**Method of measurement**

Laboratory kit

**12**

**Description**

Alkaline phosphatase (ALP)

**Timepoint**

At the beginning and at the end of week 12

**Method of measurement**

Laboratory kit

**13**

**Description**

Gamma glutamyl transferase (GGT)

**Timepoint**

At the beginning and at the end of week 12

**Method of measurement**

Laboratory kit

## 14

### **Description**

Total bilirubin

### **Timepoint**

At the beginning and at the end of week 12

### **Method of measurement**

Laboratory kit

## 15

### **Description**

Fasting blood sugar (FBS)

### **Timepoint**

At the beginning and at the end of week 12

### **Method of measurement**

Laboratory kit

## 16

### **Description**

Insulin

### **Timepoint**

At the beginning and at the end of week 12

### **Method of measurement**

Laboratory kit (ELISA)

## 17

### **Description**

Homeostatic model assessment of insulin resistance (HOMA-IR)

### **Timepoint**

At the beginning and at the end of week 12

### **Method of measurement**

Calculation: [fasting insulin (mU/L) \* fasting blood glucose (mg/dl)]/405

## 18

### **Description**

Glutathione peroxidase activity

### **Timepoint**

At the beginning and at the end of week 12

### **Method of measurement**

Laboratory kit (ELISA)

## 19

### **Description**

Adiponectin

### **Timepoint**

At the beginning and at the end of week 12

### **Method of measurement**

Laboratory kit (ELISA)

## 20

### **Description**

Serum NF-kB concentration

### **Timepoint**

At the beginning and at the end of week 12

### **Method of measurement**

Laboratory kit (ELISA)

## 21

### **Description**

NF-kB gene expression

### **Timepoint**

At the beginning and at the end of week 12

### **Method of measurement**

Real Time RT-PCR

## **Intervention groups**

### 1

#### **Description**

Intervention group: consumption of one capsule per day (containing 300 mg hydroethanolic extract of purslane) for 12 weeks

#### **Category**

Treatment - Other

### 2

#### **Description**

Control group: consumption of one placebo capsule for 12 weeks

#### **Category**

Placebo

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Rasoul akram Hospital

##### **Full name of responsible person**

Dr. Shahram Agah

##### **Street address**

Niayesh St., Sattarkhan Ave., Rasoul akram Hospital.

##### **City**

Tehran

##### **Province**

Tehran

##### **Postal code**

1445613131

##### **Phone**

+98 21 6435 1000

##### **Email**

hrmc@iums.ac.ir

##### **Web page address**

<https://hrmc.iums.ac.ir/>

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

##### **Name of organization / entity**

Iran University of Medical Sciences

##### **Full name of responsible person**

Dr. Seyyed Abbas Motevallian, deputy head of Research and Technology, Iran University of Medical

Sci

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**Phone**

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**Email**

research-m@iums.ac.ir

**Web page address**

<https://vcr.iums.ac.ir>

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Iran 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**

Iran University of Medical Sciences

**Full name of responsible person**

Dr. Farzad Shidfar

**Position**

Full Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

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**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

PhD of Nutrition

**Latest degree**

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**Other areas of specialty/work**

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**Person responsible for updating data**

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**Full name of responsible person**

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PhD of Nutrition, Full Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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## **Sharing plan**

### **Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

### **Justification/reason for indecision/not sharing IPD**

There is no further information

### **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**

Yes - There is a plan to make this available

### **Data Dictionary**

Yes - There is a plan to make this available

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

Information on the main outcomes at the end of the study can be shared.

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

### **long**

The access period will be 6 months after the publication of the results.

### **To whom data/document is available**

The data from this study will only be available to researchers working at academic and scientific institutions.

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

Six months after the publication of the articles of this project, upon request from the corresponding author and his agreement, the study data can be made available to researchers.

### **From where data/document is obtainable**

Applicants can contact the corresponding author via email or the following postal address to receive the required data. Nutrition department, School of health, Iran University of Medical Sciences, Hemmat highway, Tehran Phon number:0098 21 8862 2755 E-mail: Farzadshidfar@yahoo.com

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

Applicants will be able to access the data from the present study no later than one week by sending an email to the corresponding author.

### **Comments**