

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Effect of Purslane seeds on liver enzymes, lipid profile and FBS in patients with nonalcoholic fatty liver disease

#### Protocol summary

##### Study aim

investigate the effect of Purslane seeds on anthropometric parameters, fasting blood glucose (FBS), insulin resistance, malondialdehyde, DPPH, lipid profile and liver enzymes in patients with nonalcoholic fatty livers.

##### Design

Two arm parallel group clinical randomised trial

##### Settings and conduct

this study was a randomized clinical trial involving 60 patients with NAFLD, who referred to Najaf Abad Teachers Clinics. Participants will be divided into 2 groups, control and intervention. At the beginning and at the end of the 8th week of intervention, anthropometric parameters, three days food record, FBS, insulin resistance liver enzymes and liver sonography will be studied in both groups

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 25 to 75 years old; body mass index  $\geq 25$ ; distinction of the grade of fatty liver by sonography and understanding by doctor; do not use low caloric diet or drugs for decrease weight in 3 months; do not change in drugs for reduce lipid and hypertension during the intervention. Exclusion criteria: patients that without using 70 percent of determined Purslane seeds will be excluded from study.

##### Intervention groups

Participants will be divided into 2 groups, control and intervention. The intervention group will be asked to use 10 milligrams of purslane seeds (5 milligrams of purslane seeds before the breakfast and dinner) for 8 weeks. The patients in 2 groups will be given a diet of 500 kcal energy less than their needs in terms of their modified weights and a ratio of 30% fat, 15% protein, and 55% carbohydrate

##### Main outcome variables

FBS, Insulin resistance, HDL, TG, LDL, TOTAL Cholesterol, ALK, AST, ALT, MDA, DPPH And liver sonography

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014090210826N14**

Registration date: **2014-09-26, 1393/07/04**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-11-10, 1397/08/19**

Update count: **1**

##### Registration date

2014-09-26, 1393/07/04

##### Registrant information

##### Name

Azadeh Nadjarzadeh

##### Name of organization / entity

Shahid Sadoughi University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 912 202 2817

##### Email address

azadnajarzadeh@ssu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Yazd Shahid Sadoughi University

##### Expected recruitment start date

2014-04-04, 1393/01/15

##### Expected recruitment end date

2014-12-21, 1393/09/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

Effect of Purslane seeds on liver enzymes, lipid profile and FBS in patients with nonalcoholic fatty liver disease

**Public title**

Effect of Purslane seeds in patients with nonalcoholic fatty liver disease

**Purpose**

Treatment

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

Inclusion criteria: age between 25 to 75 years old body mass index  $\geq 25$  distinction of the grade of fatty liver by sonography and understanding by doctor not pregnant or lactating do not have any other diseases like gastrointestinal, liver, renal or thyroid disease and diabetes individuals who are not under special diet and do not participate in another intervention do not use low caloric diet or drugs for decrease weight in 3 months do not use vitamin supplements 2 months ago do not change in drugs for reduce lipid and hypertension during the intervention Exclusion criteria: patients who are not using more than 30 percent of determined Purslane seeds sachet will be excluded from study.

**Exclusion criteria:****Age**

From **25 years** old to **75 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

computerized generated random number table

**Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

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

empty

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

Ethics committee of Shahid Sadoughi University of Medical Science

**Street address**

Imam Hosein Square, Yazd

**City**

Yazd

**Province**

Yazd

**Postal code**

8916895473

**Approval date**

2014-03-01, 1392/12/10

**Ethics committee reference number**

17/1/241126/پ

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

Non alcoholic fatty liver

**ICD-10 code**

K76.0

**ICD-10 code description**

Nonalcoholic fatty liver disease (NAFLD)

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

liver supersonic graphy

**Timepoint**

before & after intervention

**Method of measurement**

radiologic picture

**2****Description**

AST

**Timepoint**

before and after intervention

**Method of measurement**

blood sample

**3****Description**

ALT

**Timepoint**

before and after intervention

**Method of measurement**

blood sample

**4****Description**

Alkaline phosphatase

**Timepoint**

before and after intervention

**Method of measurement**

blood sample

## Secondary outcomes

**1**

**Description**

weight

**Timepoint**

before and after intervention

**Method of measurement**

digital scale

**2**

**Description**

height

**Timepoint**

before and after intervention

**Method of measurement**

stadiometer,m

**3**

**Description**

waist circumference

**Timepoint**

before and after intervention

**Method of measurement**

meter,cm

**4**

**Description**

FBS

**Timepoint**

before and after intervention

**Method of measurement**

mg/dl

**5**

**Description**

Total cholesterol

**Timepoint**

before and after intervention

**Method of measurement**

mg/dl, blood sample

**6**

**Description**

LDL

**Timepoint**

before and after intervention

**Method of measurement**

mg/dl, blood sample

**7**

**Description**

HDL

**Timepoint**

before and after intervention

**Method of measurement**

mg/dl, blood sample

**8**

**Description**

Triglycerid

**Timepoint**

before and after intervention

**Method of measurement**

mg/dl, blood sample

**9**

**Description**

insulin

**Timepoint**

before and after intervention

**Method of measurement**

blood sample

**10**

**Description**

malon di aldehyd

**Timepoint**

before and after intervention

**Method of measurement**

blood sample

**11**

**Description**

DPPH

**Timepoint**

before and after intervention

**Method of measurement**

blood sample

## Intervention groups

**1**

**Description**

Intervention group: using low caloric diet (kilo caloric/ body weight) - 500.15% protein, 55% carbohydrate, 30% fat.also they use10 gr purslane seed daily for 8 weeks.

**Category**

Other

**2**

**Description**

Control group: using low caloric diet (kilo caloric/ body weight) - 500. 15% protein, 55% carbohydrate, 30% fat.

**Category**

Other

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**

Farhangian Clinic

**Full name of responsible person**

Azadeh Nadjarzadeh

**Street address**

Department of nutrition, School of public health,  
Shahid Sadoughi University of Medical Sciences, Yazd,  
Iran

**City**

Najaf Abad

**Province**

Isfahan

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+98 35 3820 9100

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azadnajarzadeh@ssu.ac.ir

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Research deputy, Shahid Sadoughi University of  
Medical Sciences

**Full name of responsible person**

Dr Hassan Mozaffari

**Street address**

Bahonar Square, Yazd

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h.mozaffari@ssu.ac.ir

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Research deputy, Shahid Sadoughi 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**

Yazd University of Medical Sciences

**Full name of responsible person**

Dr Azade Najarzadeh

**Position**

Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Nutrition

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Yazd University of Medical Sciences. Shohadaye  
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**Web page address**

## Person responsible for scientific inquiries

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**Other areas of specialty/work**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Elham Adelnia

**Position**

Master student of nutrition

**Latest degree**

Master

**Other areas of specialty/work**

Nutrition

**Street address**

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**Phone**

+98 353820910014

**Fax****Email**

adelnia.e@gmial.com

**Web page address****Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not 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**

Data report will be shared after publishing the paper

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

Six months after publish

**To whom data/document is available**

Academic researchers

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

Using for Meta-analysis

**From where data/document is obtainable**

Center nutrition, public health, univercity of medical  
sciences yazd Tel: 009835 31492239 Email:  
azadehnajarzadeh@gmail.com Azadenadjarzadeh

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

It will be sent two weeks after the receipt of the email with the consent of the co-workers

**Comments**