

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 ≥ 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 ≥ 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

Postal code

8915173160

Phone

+98 35 3820 9100

Email

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

City

Yazd

Province

Yazd

Postal code

8916895473

Phone

+98 35 3726 3733

Email

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

Street address

Yazd University of Medical Sciences. Shohadaye
Gomnam, Alalam squer, Yazd

City

Yazd

Province

Yazd

Postal code

8915173160

Phone

+98 353820910014

Fax

Email

azadnajarzadeh@ssu.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr. Azade Najarzade

Position

Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

Yazd University of Medical Sciences. Shohadaye
Gomnam, Alalam squer, Yazd

City

Yazd

Province

Yazd

Postal code

8915173160

Phone

+98 353820910014

Fax

Email

azadnajarzadeh@ssu.ac.ir

Web page address

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

Yazd University of Medical Sciences. Shohadaye
Gomnam, Alalam squer, Yazd

City

Yazd

Province

Yazd

Postal code

8915173160

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