Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Nov 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, fas ting blood glucose (FBS), insuline resistance, malon di aldehid, 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 8 th week of intervention, anthropometric parameters, three days food record, FBS, insulin resistance liver enzymes and liver sonography will studied in both groups

Participants/Inclusion and exclusion criteria
Inclusion criteria: age between 25 to75 years old; body mass index>=25; distinction of the grade of fatty liver by sonography and undrestanding 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 exclude from study.

Intervention groups
Participants will be divided into 2 groups, control and intervention.The intervention group will 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 given a diet of 500 kcal energy less than their needs in termsbof their modified weights and a ratio of 30% fat, 15% protein, and 55% carbohydrate

Main outcome variables
FBS, Insulin resistance, HDL, TG, LDL, TOTAL Cholestorl, 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

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source
Yazd Shahid Sadoghi 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 to75 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 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 genererated 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

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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.O

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
Alkalin phosphat

Timepoint
before and after intervention

Method of measurement
blood sample

Secondary outcomes

1

Description
weight
Timepoint
before avd after intervention
Method of measurement
digital scale

2

Description
hieght
Timepoint
before avd after intervention
Method of measurement
stadiometer,m

3

Description
waist circumfrence
Timepoint
before avd after intervention
Method of measurement
meter,cm

4

Description
FBS
Timepoint
before and after intervention
Method of measurement
mg/dl

5

Description
Total cholestrol
Timepoint
before and after intervention
Method of measurement
mgr/dl, blood sample

6

Description
LDL
Timepoint
before and after intervention
Method of measurement
mgr/dl, blood sample

7

Description
HDL
Timepoint
before and after intervention
Method of measurement
mgr/dl, blood sample

8

Description
Triglycerid
Timepoint
before and after intervention
Method of measurement
mgr/dl, blood sample

9

Description
insulin
Timepoint
before and after intervention
Method of measurement
blood sample

10

Description
malon di aldehid
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

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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

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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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Person responsible for scientific inquiries

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Person responsible for updating data

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Full name of responsible person
Elham Adelnia
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Latest degree
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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 sciencies 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