Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Nov 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-kB 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)

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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/m2
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 begining and at the end of week 12
Method of measurement
Laboratory kit

Secondary outcomes

1

Description
Weight
Timepoint
At the begining and at the end of week 12
Method of measurement
Seca scale

2

Description
Body mass index (BMI)
Timepoint
At the begining 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 begining 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Sci

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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
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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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 highsway, 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