Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effect of Complementary Therapy with Hydro-Ethanolic Extract of Aerial Parts of Purslane on Clinical and Paraclinical Findings in Patients with Nonalcoholic Fatty Liver Disease

Protocol summary

Study aim

Determining the effect of supplementation with hydroethanolic extract of portulaca oleracea on clinical and laboratory findings in patients with non-alcoholic fatty liver

Design

This study is a double-blind RCT that investigates the effect of supplementation with hydro-ethanolic extract of aerial parts of Purslane for eight weeks at daily dose of 700 (two capsules of 350mg) on lipid profile, inflammatory markers and oxidative stress and nutritional status and liver fibrosis and steatosis status in NAFLD patients. Study groups: intervention and control (each n = 27).

Settings and conduct

Demographic information and medical history and anthropometric indices, BP and body composition (BIA), three-day food recall and IPAQ will be measured before, between and after the study. 5 cc of blood is taken (before & after the intervention) after 12-hour fasting, to evaluate laboratory indicators. All patients will be given hypocaloric diet. Mediterranean diet recommendations and physical activity will be given. At the end, changes in the status of steatosis and liver fibrosis in patients will be assessed.

Participants/Inclusion and exclusion criteria

Inclusion: 18 to 65 years, diagnosis of hepatic steatosis, filling out the consent form exclusion: pregnancy, lactation, morbidobesity, history of alcohol consumption or hepatotoxic drugs, any immunodeficiency disorder, HIV, liver or kidney failure, other liver diseases, bariatric surgery

Intervention groups

Intervention group: lifestyle interventions (diet therapy + PA), supplementation with hydro-ethanolic extract of aerial parts of Purslane with 2 capsules each having 350 mg daily for 8 weeks.

Main outcome variables

Assessment of anthropometric indices, body composition, serum concentration of MDA, GSH, TC, HDL-C, LDL-C, TG, FBS and insulin, ALT, ALP, AST,GGT,ESR,CBC Diff and hs-CRP and 3-day food recall, IPAQ and steatosis and hepatic fibrosis status.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211116053073N1**
Registration date: **2021-12-01, 1400/09/10**
Registration timing: **prospective**

Last update: **2021-12-01, 1400/09/10**
Update count: **0**

Registration date

2021-12-01, 1400/09/10

Registrant information

Name
Narges Milkarizi
Name of organization / entity
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-24, 1400/10/03

Expected recruitment end date

2022-02-22, 1400/12/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Complementary Therapy with Hydro-Ethanolic Extract of Aerial Parts of Purslane on Clinical and Paraclinical Findings in Patients with Nonalcoholic Fatty Liver Disease

Public title

Effect of Complementary Therapy with Purslane in Nonalcoholic Fatty Liver Disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Detection of Hepatic Steatosis by Two-Dimensional Elastography Device Consent to Enter the Scheme Fatty Liver Patients with Grade F0 and F1

Exclusion criteria:

Pregnancy and Lactation Diseases such as: Diabetes, Autoimmune Disorders, Cancer, Liver Failure, Viral Hepatitis History, Liver Surgery and Renal Impairment (GFR <50) History of Food Allergy to Purslane and Herbal Supplements Taking Hepatoxic Drugs such as Amiodarone, Sodium Valproate or Methotrexate Body Mass Index more than 40 Consumption of Alcohol more than 30 grams per day for Men and also Consumption of more than 20 grams per day for Women History of Bariatric Surgery Fatty Liver Patients with F2, F3, F4 Grades Consumption of any Multivitamin Supplement and Antioxidant Compounds such as Vitamins C, E and Herbal Medicines during the Intervention Period

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **27**

Randomization (investigator's opinion)

Randomized

Randomization description

According to the Two Intervention and Control Groups, the Volume of each Block will be Four. Then Write A List of Blocks and Assign Numbers to them. For example (AABB (1)-ABAB (2)-ABBA (3)-BBAA (4)-BABA (5)-BAAB (6) which According to the Sample Size 27 The Number of People in each Group will be 9 blocks, then the Random Nnumbers between one and 9 will be Selected According to the Randomization Site Randomaize.com, and Finally the List of Treatment Allocation Based on Random Numbers will be Written on the Envelopes Containing each Block. Randomization type: Blocked How to make 4 blocks: We use letters depending on how many groups are studied For two groups of which 6 modes of movement are possible. A, B According to the formula, if there are two groups, a four-letter block for two letters and Formula 1 are used. 1. 4! (1 * 2 * 3 * 4) / [2! (1 * 2)] * [4-2]! = 3 * 4/2 = 6 states Allocation Concealment allocation method: Use of opaque SNOSE sealed envelopes (sequentially numbered, opaque, sealed envelopes) In this way, the envelopes will be prepared and printed by one of the team members and random numbers and will be placed inside the envelope. The lid of the envelope will be closed and its contents will not be visible from the outside. Then, the purpose of the study is explained to the person who meets the conditions, and the person, if desired, signs the informed consent form and takes an envelope, and then opens it and enters the intervention or control group based on the contents of the envelope.

Blinding (investigator's opinion)

Double blinded

Blinding description

Due to the use of placebo similar to the intervention treatment, the physician associated with the participants and participants will not be informed of the assigned treatment. Also, the analyst will be unaware of the treatment assigned to the two groups. Finally, after analyzing the data, the researcher who prepared the packages reveals codes A and B. With the exception of the pharmacist, none of the participants, researchers, or analysts will be aware of the drug or placebo until the end of the study. In this way, the groups are identified only by codes A and B. The drugs are prepared in the same packaging and in the same form and are packaged by a person in a pharmaceutical company that is out of research in the form of A and B coding packages. The code password is stored securely in the system so that the codes can be unlocked after data collection.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad university of medical science

Street address

Nutrition department, Faculty of medicine Mashhad University of Medical Sciences (MUMS), Azadi square,

Mashhad, Iran

City
Mashhad

Province
Razavi Khorasan

Postal code
9177948564

Approval date
2021-10-31, 1400/08/09

Ethics committee reference number
IR.MUMS.REC.1400.223

Health conditions studied

1

Description of health condition studied
non alcoholic fatty liver- hepatic steatosis and fibrosis- hydro-ethanolic extract of aerial parts of Purslane

ICD-10 code
K76.0

ICD-10 code description
Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description
hepatic steatosis and fibrosis

Timepoint
before and at the end of the study

Method of measurement
Two-dimensional elastography device

Secondary outcomes

1

Description
Measurement of anthropometric indices

Timepoint
Before, in the middle and at the end of the study

Method of measurement
Scales, meters,

2

Description
Measurement of body composition by BIA device

Timepoint
Before, in the middle and at the end of the study

Method of measurement
BIA

3

Description
Measurement of serum concentrations of oxidative stress indicators including malondialdehyde, glutathione

Timepoint
Before and at the end of the study

Method of measurement
Laboratory methods

4

Description
Evaluation of IPAQ physical activity questionnaire and three-day food recall

Timepoint
Before, in the middle and at the end of the study

Method of measurement
statistical methods

5

Description
Measurement of serum concentrations of lipid profiles including TC, HDL-C, LDL-C and TG

Timepoint
Before and at the end of the study

Method of measurement
Laboratory methods

6

Description
Measurement of serum concentrations of fasting blood glucose and insulin

Timepoint
Before and at the end of the study

Method of measurement
Laboratory methods

7

Description
Measurement of serum concentrations of hepatic profiles including ALT, ALP ,AST,GGT

Timepoint
Before and at the end of the study

Method of measurement
Laboratory methods

8

Description
Measurement of serum concentrations of inflammatory markers including ESR and Hs-CRP

Timepoint
Before and at the end of the study

Method of measurement
Laboratory methods

Intervention groups

1

Description
Intervention group: in addition to lifestyle interventions (diet therapy + physical activity), supplementation of hydro-ethanolic extract of aerial parts of Purslane with a dose of 700mg is performed for 8 weeks. Each capsule containing 350 mg of hydro-ethanolic extract of aerial

parts of Purslane is given daily with two main meals (breakfast and dinner) for 8 weeks.

Category

Treatment - Drugs

2

Description

Control group: in addition to lifestyle interventions (diet + physical activity), patients received two capsules containing 350mg placebo every day for 8 weeks with the same characteristics in terms of shape, smell, color, etc., along with two main meals (breakfast and Dinner) for 8 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital Specialized Clinic

Full name of responsible person

Dr. Ladan Goshayeshi, Dr. Mohsen Nematy

Street address

Imam Reza Hospital Specialized Clinic- Imam Reza square- Mashhad- Iran

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9137913316

Phone

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Email

Milkarizin991@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen Tafaghodi

Street address

Mashhad university of medical sciense- Azadi Square- Mashhad- Iran

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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

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Narges Milkarizi

Position

MSc student of nutrition

Latest degree

Bachelor

Other areas of specialty/work

Nutrition

Street address

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

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Position

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Latest degree

Bachelor

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Person responsible for updating data

Contact

Name of organization / entity
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Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

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
I will inform at the end of the study.

When the data will become available and for how long
I will inform at the end of the study.

To whom data/document is available
I will inform at the end of the study.

Under which criteria data/document could be used
I will inform at the end of the study.

From where data/document is obtainable
I will inform at the end of the study.

What processes are involved for a request to access data/document
I will inform at the end of the study.

Comments