Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jul 2026

The effects of flaxseed powder consumption on disease severity, biochemical, inflammatory, anthropometric, sarcopenic parameters and quality of life in patients with liver cirrhosis.

Protocol summary

Study aim

Determining the effects of flaxseed powder consumption on disease severity, biochemical, inflammatory, anthropometric, sarcopenic parameters and quality of life in patients with liver cirrhosis.

Design

A controlled, parallel-group, open-label, randomized clinical trial of 50 patients. Sealedenvelope software is used for randomization.

Settings and conduct

This international study will be conducted on cirrhotic patients with the aim of the effects of flaxseed powder on these patients at the Institute of Gastrointestinal and Liver Diseases of Shahid Beheshti University of Medical Sciences in Tehran. 25 patients in each group are divided into intervention and control groups to participate in this research. After the baseline general information registration , two stages of blood sampling are done at the beginning and 12 weeks after the start of the study in order to check the outcomes of the research, including the severity of the disease, biochemical and inflammatory parameters. Also, anthropometric and sarcopenic indicators will be measured, as well as changes in the quality of life in the above two time periods will be assessed in these people.

Participants/Inclusion and exclusion criteria

Participants: patients with liver cirrhosis Inclusion criteria: People with liver cirrhosis who may benefit from flexseed powder non inclusion criteria: Any condition that can endanger the patient's current condition

Intervention groups

The patients of the intervention group will receive 30 grams of flaxseed powder daily for 12 weeks. The patients are asked to consume a 30 gram packet every night with water, cold liquids or salad.

Main outcome variables

Severity of liver cirrhosis based on Model for end stage liver disease (MELD)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230514058189N1**
Registration date: **2023-05-19, 1402/02/29**
Registration timing: **prospective**

Last update: **2023-05-19, 1402/02/29**
Update count: **0**

Registration date

2023-05-19, 1402/02/29

Registrant information

Name

fereshteh pashayee-khamene

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3373 8319

Email address

fereshteh.pashai@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-22, 1402/04/01

Expected recruitment end date

2023-11-21, 1402/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effects of flaxseed powder consumption on disease severity, biochemical, inflammatory, anthropometric, sarcopenic parameters and quality of life in patients with liver cirrhosis.

Public title
Effects of flaxseed consumption in liver cirrhosis
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
All patients with liver cirrhosis whose cirrhosis has been confirmed by a specialist physician.
Exclusion criteria:
Those who have other extrahepatic diseases at the same time.
Age
From **18 years** old to **75 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, the block randomization method is used individually using sealedenvelope software. In order to hide the order of the codes, they are placed in closed envelopes so that the researcher does not know the order of the codes for the entry of people into the intervention or control group.
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 Ahvaz jundi shapour University of Medical Sciences
Street address
jundishapour university of medical sciences, golestan, ahvaz
City
Ahvaz
Province
Khouzestan
Postal code
15794-61357
Approval date
2023-05-08, 1402/02/18
Ethics committee reference number
IR.AJUMS.REC.1402.090

Health conditions studied

1

Description of health condition studied
liver cirrhosis
ICD-10 code
K74
ICD-10 code description
Fibrosis and cirrhosis of liver

Primary outcomes

1

Description
Severity of liver cirrhosis according to Model for end stage liver disease score (MELD)
Timepoint
Measurement of disease severity based on the MELD score before and 12 weeks after the start of flaxseed powder consumption
Method of measurement
Calculation of MELD using the formula and variables of bilirubin, creatinine and INR

Secondary outcomes

1

Description
Cirrhosis severity score based on child-Pugh
Timepoint
Measurement of mean cirrhosis severity based on child-Pugh score before and 12 weeks after flaxseed powder consumption
Method of measurement
child-Pugh calculation formula using the variables of bilirubin, albumin, INR (international normalized ratio), presence or absence of ascites and encephalopathy

2

Description
Level of serum total cholesterol
Timepoint
Measurement of mean level of serum total cholesterol before and 12 weeks after flaxseed powder consumption
Method of measurement
Auto Analyzer and Total Cholesterol Test Kit (Biorex)

3

Description
Level of serum low density lipoprotein (LDL)
Timepoint
Measurement of mean level of serum LDL before and 12 weeks after flaxseed powder consumption
Method of measurement
Auto Analyzer and LDL Test Kit (Biorex)

4

Description
Level of serum high density lipoprotein (HDL)
Timepoint
Measurement of mean level of HDL before and 12 weeks after flaxseed powder consumption
Method of measurement
Auto Analyzer and HDL Test Kit (Biorex)

5

Description
Level of serum triglyceride (TG)
Timepoint
Measurement of mean level of serum TG before and 12 weeks after flaxseed powder consumption
Method of measurement
Auto Analyzer and TG Test Kit (Biorex)

6

Description
Level of serum fasting blood sugar (FBS)
Timepoint
Measurement of mean level of FBS before and 12 weeks after flaxseed powder consumption
Method of measurement
Auto Analyzer and FBS Test Kit (Biorex)

7

Description
Level of serum insulin
Timepoint
Measurement of mean level of serum insulin before and 12 weeks after flaxseed powder consumption
Method of measurement
Enzyme-linked immunosorbent double- antibody sandwich assay and insulin Test Kit (monobind)

8

Description
Homeostatic Model Assessment (HOMA-IR) index
Timepoint
Measurement of HOMA-IR before and 12 weeks after flaxseed powder consumption
Method of measurement
HOMA-IR calculation formula

9

Description
Quantitative insulin sensitivity check index (QUICKI)
Timepoint
Measurement of QUICKI before and 12 weeks after flaxseed powder consumption
Method of measurement
QUICKI calculation formula

10

Description
Level of serum total bilirubin
Timepoint
Measurement of mean level of serum total bilirubin before and 12 weeks after flaxseed powder consumption
Method of measurement
Auto Analyzer and total bilirubin Test Kit (Biorex)

11

Description
Level of serum albumin
Timepoint
Measurement of mean level of serum albumin before and 12 weeks after flaxseed powder consumption
Method of measurement
Auto Analyzer and albumin Test Kit (Biorex)

12

Description
Level of serum gamma-glutamyl transferase (GGT)
Timepoint
Measurement of mean level of serum GGT before and 12 weeks after flaxseed powder consumption
Method of measurement
Auto Analyzer and GGT Test Kit (Biorex)

13

Description
Level of serum creatinine
Timepoint
Measurement of mean level of serum creatinine before and 12 weeks after flaxseed powder consumption
Method of measurement
Auto Analyzer and creatinine Test Kit (Biorex)

14

Description
Level of serum sodium
Timepoint
Measurement of mean level of serum sodium before and 12 weeks after flaxseed powder consumption
Method of measurement
standard solution Na

15

Description
Prothrombin time (PT)
Timepoint
Measurement of PT before and 12 weeks after flaxseed

powder consumption

Method of measurement

manual

16

Description

Partial prothrombin time (PTT)

Timepoint

Measurement of PTT before and 12 weeks after flaxseed powder consumption

Method of measurement

manual

17

Description

International normalized ratio (INR)

Timepoint

Measurement of INR before and 12 weeks after flaxseed powder consumption

Method of measurement

Manual

18

Description

level of serum High-sensitivity C-reactive Protein (hs-CRP)

Timepoint

Measurement of serum hs-CRP before and 12 weeks after flaxseed powder consumption

Method of measurement

Enzyme-linked immunosorbent double- antibody sandwich assay and hs-CRP Test Kit (Zelbio)

19

Description

Level of serum apelin

Timepoint

Measurement of serum apelin before and 12 weeks after flaxseed powder consumption

Method of measurement

Enzyme-linked immunosorbent double- antibody sandwich assay and apelin Test Kit (Zelbio)

20

Description

body weight

Timepoint

Measurement of body weight mean before and 12 weeks after flaxseed powder consumption

Method of measurement

weight scale

21

Description

body mass index (BMI)

Timepoint

Measurement of BMI mean before and 12 weeks after flaxseed powder consumption

Method of measurement

Calculation by formula

22

Description

lean body mass (LBM)

Timepoint

Measurement of LBM mean before and 12 weeks after flaxseed powder consumption

Method of measurement

using of body analyzer (in body 270)

23

Description

fat mass (FM)

Timepoint

Measurement of FM mean before and 12 weeks after flaxseed powder consumption

Method of measurement

using of body analyzer (in body 270)

24

Description

fat mass percent (FM%)

Timepoint

Measurement of FM% mean before and 12 weeks after flaxseed powder consumption

Method of measurement

using of body analyzer (in body 270)

25

Description

muscle strength

Timepoint

Measurement of muscle strength mean before and 12 weeks after flaxseed powder consumption

Method of measurement

using hand grip dynamometer (jamar hydraulic hand dynamometer B001D7QDJG)

26

Description

muscle arm circumference (MAC)

Timepoint

Measurement of MAC mean before and 12 weeks after flaxseed powder consumption

Method of measurement

using tape

27

Description

triceps skinfold thickness (TSF)

Timepoint

Measurement of TSF mean before and 12 weeks after flaxseed powder consumption

Method of measurement

using caliper (Harpenden skinfold caliper FG1056)

28

Description
frailty
Timepoint
Measurement of frailty mean before and 12 weeks after flaxseed powder consumption
Method of measurement
using liver frailty index (LFI) questionnaire

29

Description
sarcopenia
Timepoint
Measurement of sarcopenia mean before and 12 weeks after flaxseed powder consumption
Method of measurement
using Strength, assistance with walking, rising from a chair, climbing stairs, and falls questionnaire (SARC-F)

30

Description
quality of life score
Timepoint
Measurement of mean quality of life score before and 12 weeks after flaxseed powder consumption
Method of measurement
using 36-Item Short Form Survey (SF-36) questionnaire

31

Description
Mid arm muscle arm circumference (MAMC)
Timepoint
Measurement of MAMC mean before and 12 weeks after flaxseed powder consumption
Method of measurement
Calculation by formula using muscle arm circumference (MAC) and triceps skinfold thickness (TSF)

Intervention groups

1

Description
Intervention group: Patients in the intervention group will receive 30 grams of flaxseed powder daily for 12 weeks. Fresh flaxseed will be prepared and ground from Zarin giyahine store. 30 gram packages of flaxseed powder with the relevant packaging and label have been prepared and the consumption amount for one month will be provided to the patients. Patients are asked to consume one 30 gram packet every night with water, cold liquids or salad.
Category
Treatment - Other

2

Description
Control group: patients in the control group do not receive any food or placebo and the study is open labeled.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Research Institute of Gastrointestinal and Liver Diseases, Shahid Beheshti University of Medical Sci
Full name of responsible person
Behzad Hatami
Street address
Ayatollah Taleghani Hospital-Shahid Arabi Street-Yemen Street- Shahid Chamran Highway- Tehran
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Province
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Phone
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Email
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Sahand Jorfi
Street address
Ahvaz Jundishapur University of Medical Sciences، Deputy of research and technology،Ahvaz, Iran
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3336 2414
Email
itc@ajums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Fatemeh Haidari
Position
Professor
Latest degree
Ph.D.
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Person responsible for updating data

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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
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available