Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 2026

To survey the effect of L-carnitine supplement on frailty index in liver cirrhotic adult patients and compare to control group: A double-blind randomized control trial

Protocol summary

Study aim
Determining the effect of L-carnitine supplementation on frailty index in adult liver cirrhotic patients

Design
This study is a double-blind, randomized controlled trial with a parallel-group conducted on adult cirrhotic patients in Shiraz Abu Ali Sina Hospital (Shiraz Organ Transplantation Center). In this study, the effect of L-carnitine on the frailty index in patients with liver cirrhosis will be investigated. The intervention group consisted of 35 patients taking L-carnitine with conventional medications and the control group of 35 patients receiving only conventional medications.

Settings and conduct
This study is a double-blind, randomized controlled clinical trial using L- carnitine supplementation among adult patients with liver cirrhosis in the clinic of Shiraz Bu Ali Sina Hospital. The medical students and a gastroenterologist will examine the patient and evaluate the laboratory tests, and frailty index under blinded conditions. The data analyzer is also unaware of case and control groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Adult patients(18-50 years old), Cirrhotic patients Exclusion criteria: Overt hepatic encephalopathy, Consumption of L-carnitine supplement in the last year, Hepatocellular carcinoma, Decompensated cirrhosis, MELD more than 20, HbA1c more than7

Intervention groups
The dose of L-carnitine 500 mg orally three times a day for two months will be given to the patient along with the conventional medication regimen. the control group with a sample size of 35 cirrhotic patients who were matched with the intervention group based on age, sex, underlying disease, and MELD score taking the conventional medication regimen.

Main outcome variables
Liver frailty index

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20200628047940N2**
Registration date: **2022-06-14, 1401/03/24**
Registration timing: **registered_while_recruiting**

Last update: **2022-06-14, 1401/03/24**
Update count: **0**

Registration date
2022-06-14, 1401/03/24

Registrant information
Name
Nasrin Motazedian
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2022-01-30, 1400/11/10
Expected recruitment end date
2022-06-21, 1401/03/31
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

To survey the effect of L-carnitine supplement on frailty index in liver cirrhotic adult patients and compare to control group: A double-blind randomized control trial

Public title

L-carnitine supplement in end-stage liver disease adult patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Adult patients(18-50 years old) Cirrhotic patients

Exclusion criteria:

Overt hepatic encephalopathy Consumption of L-carnitine supplement in the last year Hepatocellular carcinoma Decompensated cirrhosis MELD more than 20 HbA1c more than7

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients with liver cirrhosis who refer to the inpatient clinic of Abu Ali Sina Transplant Hospital, are examined by a gastroenterologist. If they have inclusion criteria and are willing to participate in the study, they are referred to a medical student to record patient information and measure the frailty index. Patients go to the pharmacy to receive medicine. The patients are divided into the intervention and control groups according to the order of referral, using the supplemental block list by a physician in charge of the pharmacy. The intervention group will receive L-carnitine from the pharmacy according to the list. Randomization method: Permutation block design or quadruple blocks will be used. We assign different permutations to numbers 1 to 6 in the following order. 1. AABB 2. ABAB 3. ABBA 4. BBAA 5. BABA 6. BAAB Then, using the table of random numbers, we extract the numbers from the table and depending on which one of the numbers 1 to 6 comes, select each of the blocks assigned to these numbers until 19 blocks of 4 are selected. If the numbers are zero, 7, 8, and 9, we will ignore them and continue this order to provide a complete list for the entire sample size.

Blinding (investigator's opinion)

Double blinded

Blinding description

The medical students and a gastroenterologist will examine the patient and evaluate the laboratory tests, and frailty index under blinded conditions. The data analyzer is also unaware of case and control groups.

Placebo

Not used

Assignment

Parallel

Other design features

There is no spesific information.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Ethics Commitee, Shiraz University of Medical Sciences, Zand Street, Beside Helal Ahmar, Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

71348-14336

Approval date

2022-01-05, 1400/10/15

Ethics committee reference number

IR.SUMS.MED.REC.1400.540

Health conditions studied

1

Description of health condition studied

liver cirrhosis

ICD-10 code

K74.60 - A

ICD-10 code description

K74- Fibrosis and cirrhosis of liver › 2022 ICD-10-CM Diagnosis Code K74.69.

Primary outcomes

1

Description

Frailty

Timepoint

before intervention, after 2 months

Method of measurement

Liver frailty index. The liver frailty index will be used in the evaluation of frailty in patients with cirrhosis. This

criterion consists of three parts. The Frilati Liver Index consists of three performance-based tests (grip strength, chair stands, and balance), a tool that measures physical function specifically in patients with cirrhosis.

Secondary outcomes

1

Description
Hepatic encephalopathy
Timepoint
Before intervention and 2, months after intervention
Method of measurement
Clinical examination, and lab data

2

Description
Creatinine level
Timepoint
before intervention, and 2 months after intervention
Method of measurement
lab data

Intervention groups

1

Description
The intervention group receives the L-carnitine supplement (b-hydroxy-gN-trimethylamino-butyric acid), an essential nutrient in the diet. The main function of L-carnitine in cellular energy metabolism, and as an essential element in the transfer of long-chain fatty acids to the inner mitochondrial membrane and the site of beta oxidation. The dose of L-carnitine 500 mg capsule orally three times a day for two months will be given to the patient along with the conventional medication regimen. British Life Plan manufacturer, importer of Nikan Pharmed Mehr Company
Category
Other

2

Description
Among patients who have the inclusion criteria and are willing to participate in the study, 35 patients are considered as a control group according to the block list. They will receive conventional medication regimens from pharmacies.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Shiraz Transplant Research Center
Full name of responsible person
Nasrin Motazedian
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Seventh floor, Transplant Research Center, Research Tower, Mollasadra St., Khalili Ave., Shiraz, IR Iran.
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Shiraz Transplant Research Center
Proportion provided by this source
80
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
Shiraz University of Medical Sciences

Full name of responsible person
Nasrin Motazedian

Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
Public Health/Community Medicine

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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 more information

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
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available