

# 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 than 7

##### 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

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3628 1529

##### Email address

nmotazedi@sums.ac.ir

##### 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 specific information.

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

##### Street address

Ethics Committee, 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

#### Street address

Seventh floor, Transplant Research Center, Research Tower, Mollasadra St., Khalili Ave., Shiraz, IR Iran.

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#### Province

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#### Postal code

71867

#### Phone

+98 71 3628 1529

#### Email

motazediann@yahoo.com

#### Web page address

<https://strc.sums.ac.ir>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Shiraz Transplant Research Center

##### Street address

7th floor, Transplant Research Center, Mohammad Rasool Allah Reserch Tower, Khalili Ave., Shiraz.

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##### Province

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##### Postal code

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##### Phone

+98 71 3628 1529

##### Email

transrsh@sums.ac.ir

##### Web page address

<https://strc.sums.ac.ir/>

#### 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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## Person responsible for updating data

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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**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Community Medicine

**Street address**

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of Medical Sciences, Shiraz, Iran

**City**

Shiraz

**Province**

Fars

**Postal code**

## 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