Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation the effects of L Carnitine on quality of life of the cirrhotic patients

Protocol summary

Study aim

1. Determine the effects of L Carnitine on Child score in cirrhotic patients 2. Determine the effects of L Carnitine on MELD score in cirrhotic patients 3. Determine the effects of L Carnitine on abdominal symptoms in cirrhotic patients 4. Determine the effects of L Carnitine on fatigue in cirrhotic patients 5. Determine the effects of L Carnitine on systemic symptoms in cirrhotic patients 6. Determine the effects of L Carnitine on activity in cirrhotic patients 7. Determine the effects of L Carnitine on emotional function in cirrhotic patients 8. Determine the effects of L Carnitine on worry in cirrhotic patients 9. Determine the effects of L Carnitine on sarcopenia in cirrhotic patients

Design

120 cirrhotic patients who referred to liver clinic of Taleghani hospital will be enroll in this study. Our study is triple blind and simple randomized in pahse 3 of clinical trial.1000 mg and 2000 mg daily L-carnitine will be orally administered for 24 weeks in two separate interventional groups and placebo will be used in control group.

Settings and conduct

Study will be done in liver clinic of Taleghani hospital.Demographic data, Lab tests, ascites, encephalopathy, MELD and Child scores, sarcopenia and quality of life will be evaluated at the beginning, 3 months later and six months later. Random assigning will be done by one of our research team and patients, medical doctor and statistician are blind in this study.

Participants/Inclusion and exclusion criteria

Cirrhotic patients who referred to liver clinic of Taleghani hospital with age 18-70 years old and known cause of cirrhosis with child score A or B

Intervention groups

1000 mg daily orally L carnitine 2000 mg daily orally L carnitine

Main outcome variables

Lab tests, ascites, encephalopathy, MELD and Child scores, sarcopenia (gripe strength and muscle mass), quality of life

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180313039075N1**
Registration date: **2021-01-03, 1399/10/14**
Registration timing: **registered_while_recruiting**

Last update: **2021-01-03, 1399/10/14**
Update count: **0**

Registration date

2021-01-03, 1399/10/14

Registrant information

Name
Leila Pasharavesh
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 2254 2304
Email address
leila_lp@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-12-21, 1399/10/01

Expected recruitment end date

2021-06-21, 1400/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation the effects of L Carnitine on quality of life of the cirrhotic patients

Public title
Evaluation the effects of L Carnitine on quality of life of the cirrhotic patients

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Cirrhotic patients who referred to Liver clinic of Taleghani hospital with age 18-70 years old Cirrhotic patients who referred to Liver clinic of Taleghani hospital with known case of cirrhosis Cirrhotic patients who referred to Liver clinic of Taleghani hospital with Child score A or B Cirrhotic patients who referred to Liver clinic of Taleghani hospital with no administration of L-Carnitine before

Exclusion criteria:
Not tolerate use of L-Carnitine because of the gastrointestinal problem Gastrointestinal bleeding Uncontrolled malignant tumors Need of hemodialysis Pregnancy Receiving drugs causing hyperammonemia Overt hepatic encephalopathy Patients who do not accept to continue the study Patients with other significant background diseases (heart failure, chronic kidney disease,...)

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description
120 cirrhotic patients who referred to liver clinic of Taleghani hospital with age 18-70 years old and known cause of cirrhosis with child score A or B and based on inclusion and exclusion criteria will enroll in this study. They will be assigned in three groups with simple randomization. At the end each group will contain 40 patients.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Random assigning will be done by one of our research team and patients, medical doctor and statistician are blind in this study.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of research institute for gastroenterology and hepatology

Street address
Arabi st., Velenjak, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1985717413

Approval date
2020-12-09, 1399/09/19

Ethics committee reference number
IR.SBMU.RIGLD.REC.1399.049

Health conditions studied

1

Description of health condition studied
Liver cirrhosis

ICD-10 code
K70, K74

ICD-10 code description
Cirrhosis of the liver

Primary outcomes

1

Description
Quality of life

Timepoint
First, 3 months later, 6 months later

Method of measurement
Standard questionnaire for quality life in cirrhotic patients

2

Description
Sarcopenia

Timepoint
First, 3 months later, 6 months later

Method of measurement
Evaluate gripe strength by dynamometer and muscle mass by bioelectrical impedance analysis (BIA).

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: 1000 mg L Carnitine by Zist Takhmir company will use daily for 24 weeks
Category
Treatment - Drugs

2

Description
Intervention group 2: 2000 mg L Carnitine by Zist Takhmir company will use daily for 24 weeks
Category
Treatment - Drugs

3

Description
Control group: Placebo by Zist Takhmir company will use daily for 24 weeks
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Taleghani hospital
Full name of responsible person
Leila Pasharavesh
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
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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
Zist takhmir company
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Leila Pasharavesh
Position
medical doctor, Researcher
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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
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
Yes - There is 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
Title and more details about the data/document
data sharing at end of the study
When the data will become available and for how long
At end of the study
To whom data/document is available
researchers
Under which criteria data/document could be used
for other researches
From where data/document is obtainable
Research institute for Gastroenterology and Liver Diseases of SBMU
What processes are involved for a request to access data/document
contact with this study researchers
Comments