

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Evaluation of the efficacy and safety of L-carnitine in improving liver function in liver injury

Protocol summary

Study aim

Evaluation of the efficacy and safety of oral L-carnitine in improving liver function in liver injury

Design

A randomized, placebo-controlled, double-blinded, parallel phase 3 clinical trial

Settings and conduct

In this phase 3 randomized double-blind placebo-controlled clinical trial, 100 eligible patients admitted to Baqiyatullah Hospital, who have obtained free and informed consent, will participate in the study. Patients will be randomly assigned to intervention and control groups with a ratio of 1:1 and will receive the desired intervention. Each patient will be in the study for 5 days. For the purpose of blinding, a placebo with a completely similar appearance was prepared by the drug manufacturer (Bonyan Salamat Kasra).

Participants/Inclusion and exclusion criteria

Inclusion criteria: The patient must be over 18 years old; The patient's Child-Pugh score is category B and C; The patient or his / her companion has informed and free written consent to participate in the study. Exclusion criteria: Pregnancy; Breastfeeding; History of previous allergies to any of the active ingredients of the drug; Concomitant presence in another clinical study;

Intervention groups

Intervention group: oral vial L-carnitine 2gr, 1 oral vial, every 12 hours, for 5 days. Placebo group: oral vial Placebo 2gr, 1 oral vial, every 12 hours, for 5 days.

Main outcome variables

Changes in serum level of ALT enzyme; Changes in serum level of AST enzyme;

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20080901001165N69**

Registration date: **2022-09-16, 1401/06/25**

Registration timing: **prospective**

Last update: **2022-09-16, 1401/06/25**

Update count: **0**

Registration date

2022-09-16, 1401/06/25

Registrant information

Name

Yunes Panahi

Name of organization / entity

Baqiyatallah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8821 1524

Email address

yunespanahi@bmsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-23, 1401/07/01

Expected recruitment end date

2022-12-22, 1401/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy and safety of L-carnitine in improving liver function in liver injury

Public title

Evaluation of the efficacy and safety of L-carnitine in

improving liver function in liver injury

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Have read and signed a written informed consent to participate in the study Age between 18-90 years old;
The patient's Child-Pugh score is category B or C;
Exclusion criteria:
Pregnancy; Breastfeeding; Participate in another clinical trial at the same time; History of previous allergies to any of the components of the drug;

Age
From **18 years** old to **90 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
The Block Randomization method is used to randomize the patients. For randomization, we visited www.sealedenvelope.com, then the randomization tab and make a list option were selected, the number of intervention groups, sample size, block size (which was selected due to the small sample size, 4)were entered the intended locations, then a random list containing the pattern of patient allocation was obtained in two intervention.

Blinding (investigator's opinion)
Double blinded

Blinding description
The placebo looks the same as the original drug, provided by the drug company. In this study, the prescribing physician, patient, therapeutic team, and statistical analyzer are unaware of the type of intervention (intervention/placebo).

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Baqiyatallah Hospital

Street address
Baqiyatallah Hospital, Sheykh-e-Baha'ee, Sare Mollasadra

City
Tehran

Province
Tehran

Postal code
1435915371

Approval date
2022-03-12, 1400/12/21

Ethics committee reference number
IR.BMSU.BAQ.REC.1400.074

Health conditions studied

1

Description of health condition studied

Diseases of liver

ICD-10 code

K76.9

ICD-10 code description

Liver disease, unspecified

Primary outcomes

1

Description

AST serum level

Timepoint

Before and after intervention

Method of measurement

Blood sample

2

Description

ALT serum level

Timepoint

Before and after intervention

Method of measurement

Blood sample

Secondary outcomes

1

Description

Bilirubin serum level

Timepoint

Before and after the intervention

Method of measurement

Blood sample

2

Description

Child-Pugh score

Timepoint

Before and after the intervention

Method of measurement

Child-Pugh score classification

Intervention groups**1****Description**

Intervention group: L-carnitine oral vial containing 2 grams of L-carnitine drug, 1 orally every 12 hours, for 5 days. This drug is produced by the Bonyan Salamat Kasari pharmaceutical company.

Category

Treatment - Drugs

2**Description**

Control group: oral vial placebo 2gr, every 12 hours one oral vial, for 5 days

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Baqiyatallah Hospital

Full name of responsible person

Yunes Panahi

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Mollasadra Street, Vanak Square

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Bonyan Salamat Kasra pharmaceutical company

Full name of responsible person

Ahmad Fazeli

Street address

597plaque, Hedarkhani intersection, Farjam street ,
Resalat square, Tehran

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Mahboubi1357@yahoo.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Bonyan Salamat Kasra pharmaceutical company

Proportion provided by this source

20

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

2**Sponsor****Name of organization / entity**

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Seyed Mohammad Zarei Abarghouee

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Baqiyatallah University of Medical Science, Mollasadra
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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

Bagheiat-allah University of Medical Sciences

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
Tehran University of Medical Sciences
Full name of responsible person
parisa kianpour
Position
Fellowship in Critical care Pharmacotherapy
Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for scientific inquiries

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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