Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the complementary effect of L-carnitine and placebo on the clinical outcomes of patients with COVID-19 (2019-nCov) admitted to the intensive care unit

Protocol summary

Study aim
Evaluation of the complementary effect of L-carnitine on the clinical consequences of patients with COVID-19 (2019-nCov) hospitalized in the intensive care unit

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, on 42 patients. Randomization method will be using randomized blocks produced by the online site (www.sealedenvelope.com).

Settings and conduct
The place of present project is in the intensive care unit of Imam Reza Hospital in Mashhad. In this study, people over the age of 18 with COVID-19 are randomly divided into two groups receiving medication or placebo for 7 days. The study is a double-blind study in which the patient and the intervene are kept blind.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Acute Respiratory Infection from COVID-19, Age 18-65 years old, Tendency to participate in study Non inclusion criteria: Covid-19 with mold diarrhea, history of L-carnitine allergy, use of anticonvulsant drugs, hemodialysis

Intervention groups
Intervention group: 3000 mg L-carnitine supplement, Control group: Pasteurized drinking water that is randomly packaged and covered (blinding) is gavaged to patients for 7 days

Main outcome variables
Mortality within the intensive care unit; the number of days of ventilator dependence; sepsis; respiratory distress

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20151108024938N3**
Registration date: **2023-08-21, 1402/05/30**
Registration timing: **retrospective**

Last update: **2023-08-21, 1402/05/30**
Update count: **0**

Registration date
2023-08-21, 1402/05/30

Registrant information

Name
Alireza Sedaghat

Name of organization / entity
Mashhad university of medical science

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-04-20, 1399/02/01

Expected recruitment end date
2020-09-22, 1399/07/01

Actual recruitment start date
2022-03-21, 1401/01/01

Actual recruitment end date
2023-03-21, 1402/01/01

Trial completion date
2023-07-23, 1402/05/01

Scientific title
Comparison of the complementary effect of L-carnitine and placebo on the clinical outcomes of patients with

COVID-19 (2019-nCov) admitted to the intensive care unit

Public title
Effect of L-carnitine on COVID-19
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
All patients COVID-19, admitted to intensive care unit Age 18-65 years old Satisfaction to participate in the study
Exclusion criteria:
Covid-19 with mold diarrhea History of L-carnitine allergy Use of anticonvulsant drugs Hemodialysis
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **42**
Actual sample size reached: **42**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization , block method. Randomization was performed by random block method using statistical software. In order to apply concealment in the randomization process, unique codes will be used on drug boxes, the desired code is also generated by the online site.
Blinding (investigator's opinion)
Double blinded
Blinding description
The patient, medical staff, and interventionist are all aware of the type of study and the contents of the medication and placebo packages, and only the fact that the codes of the medications remain hidden from these individuals.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Mashhad University of Medical Sciences, Faculty of Medicine, Azadi Square
City
Mashhad
Province
Razavi Khorasan
Postal code
91388-13944
Approval date
2020-04-11, 1399/01/23
Ethics committee reference number
IR.MUMS.REC.1399.026

Health conditions studied

1

Description of health condition studied
Acute respiratory infection caused by coronavirus
ICD-10 code
U07.2
ICD-10 code description
COVID-19, virus not identified

2

Description of health condition studied
Acute respiratory infection caused by coronavirus
ICD-10 code
U07.1
ICD-10 code description
COVID-19, virus identified

Primary outcomes

1

Description
Ventilator dependence
Timepoint
Before and 7 days after intervention
Method of measurement
Using ABG and the opinion of an anesthesiologist

2

Description
C-reactive protein (CRP)
Timepoint
Before and 7 days after intervention
Method of measurement
Quantitative method, by ELISA method

Secondary outcomes

1

Description
Mortality within the intensive care unit
Timepoint

Before intervention and 7 days after intervention

Method of measurement

Observe the occurrence

2

Description

The ratio of neutrophils to lymphocytes

Timepoint

Before intervention and 7 days after intervention

Method of measurement

Using a complete blood test

3

Description

Blood levels of lactate dehydrogenase

Timepoint

Before intervention and 7 days after intervention

Method of measurement

Enzymatic method

4

Description

The incidence of sepsis

Timepoint

Before intervention and 7 days after intervention

Method of measurement

Based on the diagnosis of the treating physician and SIRS criteria

5

Description

The incidence of respiratory distress

Timepoint

Before intervention and 7 days after intervention

Method of measurement

Based on the diagnosis of the treating physician and SIRS criteria

Intervention groups

1

Description

Intervention group: Receiver of 3000 mg of L-carnitine daily for 7 days by gavage from Kasra-zist takhmir bonyan company

Category

Treatment - Drugs

2

Description

Control group: Receiving 10 cc pasteurized drinking water daily for 7 days

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza hospitals

Full name of responsible person

Alireza sedaghat

Street address

Emam reza hospital; Daneshgah avenue

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Sponsors / Funding sources

1

Sponsor

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Mashhad University of Medical Sciences

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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

Mashhad 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
Mashhad University of Medical Sciences
Full name of responsible person
Seyed Mostafa Arabi
Position
PhD student
Latest degree
Master
Other areas of specialty/work
Nutrition
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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
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