

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 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)

Phone

+98 51 3802 3701

Email address

sedaghatar@mums.ac.ir

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

City

Mashhhad

Province

Razavi Khorasan

Postal code

91778-99191

Phone

+98 51 3802 3701

Fax

+98 51 3871 3638

Email

SedaghatAr@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Alireza sedaghat

Street address

Mashhad University of Medical Sciences; Azadi square

City

Mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3841 2081

Email

sedaghatar@mums.ac.ir

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

9138813944

Person responsible for general inquiries

Phone

+98 51 3882 7033

Email

arabim941@mums.ac.ir

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

Street address

Mashhad University of Medical Sciences; Azadi square

City

Mashhad

Province

Razavi Khorasan

Postal code

913881394

Phone

+98 51 3882 8574

Email

arabim941@mums.ac.ir

Person responsible for updating data

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

Street address

Mashhad University of Medical Sciences; Azadi square

City

mashhad

Province

Razavi Khorasan

Postal code

9138813944

Phone

+98 51 3882 8574

Email

arabim941@mums.ac.ir

Person responsible for scientific 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

Street address

Mashhad University of Medical Sciences; Azadi square

City

mashhad

Province

Razavi Khorasan

Postal code

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