Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of L-carnitine supplementation on mortality and serum levels of C-reactive protein in obese patients with coronavirus (nCov-2019) with acute respiratory failure admitted to intensive care unit

Protocol summary

Study aim
The effect of L-carnitine supplementation on mortality and serum levels of C-reactive protein in obese patients with coronavirus (nCov-2019) with acute respiratory failure admitted to the intensive care unit

Design
Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 40 patients. Numbers in closed envelopes were used for randomization.

Settings and conduct
A total of 40 adult patients with acute coronavirus-induced respiratory infection admitted to the Army Hospital ICU referred by an Intensive Care Specialist will be enrolled in the study after obtaining informed consent to participate in the study. Entry of each patient into the case or control group will be random and with the help of numbers in closed envelopes. Commercial L 3-carnitine capsule supplement with a dose of 3000 mg and starch as a placebo that is randomly packed and covered (blinding) is gavaged to patients for 7 days.

Participants/Inclusion and exclusion criteria
Obese men and women; over the age of 18; with acute respiratory failure due to coronavirus; hospitalized in the intensive care unit; individuals who wish to participate if they have no history of liver or kidney disease and are not pregnant or breastfeeding.

Intervention groups
Oral supplement with a high dose of L- carnitine (3000 mg) in patients with acute coronavirus-induced respiratory infection in the intensive care unit

Main outcome variables
Evaluation of ICU mortality, 28-day mortality, serum level of acute-phase reactive protein CRP, the ratio of serum level of acute-phase reactive protein level C to albumin, the number of ventilator-dependent days

General information

Reason for update
In order to increase the accuracy of the study and improve its design, according to the suggestions of clinical guidance professors, the present plan was updated.

Acronym

IRCT registration information
IRCT registration number: **IRCT20220418054581N1**
Registration date: **2022-06-11, 1401/03/21**
Registration timing: **prospective**

Last update: **2022-08-14, 1401/05/23**
Update count: **1**

Registration date
2022-06-11, 1401/03/21

Registrant information

Name
Vahid Hadi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-07-23, 1401/05/01

Expected recruitment end date
2022-12-21, 1401/09/30

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of L-carnitine supplementation on mortality and serum levels of C-reactive protein in obese patients with coronavirus (nCov-2019) with acute respiratory failure admitted to intensive care unit

Public title
Effect of L-carnitine on mortality in obese patients with coronavirus
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Patients over 18 years Diagnosis of clinical and laboratory signs of severe Covid-19 Body mass index above 29.9 kg per square meter based on the weight in the file Completion of the informed consent form by the patient or his / her legal guardian Severe COVID-19 patients who are admitted to the medical ICU (MICU) and will require respiratory support Patients with normal GI function who receive enteral feeding
Exclusion criteria:
Receive any L-carnitine supplement in the last 6 months Participate in any other research project History of liver and kidney disease Pregnancy and lactation Any allergy to L-carnitine Patients who stayed in the ICU for < 72 hours Patients who receive parenteral nutritional support Patients treated with different drug regimens from the routine ICU protocol Patients will be ongoing treatment with cisplatin, phenobarbital, phenytoin, pivalic acid, valproic acid, ifosfamide, and levetiracetam Any gastrointestinal disorders that lead to stopping enteral feeding for more than 48 hours
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
After admitting the patient to the intensive care unit and obtaining the eligible criteria for inclusion in the study, individuals were randomly assigned envelopes containing unique codes generated by the standard site (www.sealedenvelope.com). Codes with groups (A and B) were initially produced by one of the project facilitators who is not involved in any clinical phases of intervention and sampling and will remain with them until the end of the study and other researchers until the end of the study of the concept of codes and the groups will remain uninformed. On the envelopes, only the codes A or B are inserted to specify two separate groups. After assigning each envelope to the patient admitted to the study, the envelope is opened and the code inside the envelope, which contains two letters and a number (for example, XY3), which has no meaning and does not indicate any meaning, and is completely random, will be inserted on the supplement box. Patients are only classified according to code A or B, and the numbers in the envelope are not a criterion for classification or indication of belonging to a specific group. These codes are used only for labeling on medicine and placebo BOXS.
Blinding (investigator's opinion)
Double blinded
Blinding description
The drugs and placebos in this study are exactly the same. In the present study, L-carnitine and placebo capsules are produced in exactly the same volume, color, odor, and size and are provided to the nurse or nutritionist in the same package. All researchers conducting the study, nurses, physicians, and data collectors will be kept blind to the type of supplements and groups assigned. As each patient enters the study, an envelope containing the code is randomly selected, and after opening the envelope, the code inside it is recorded on the supplement box of the same group as the code on the envelope and is assigned to the patient. Therefore, before and after selecting the patient, none of the researchers and the clinical team will be aware of the type of supplement the patient is receiving.After assigning a supplement or placebo to the patient, the nurse dissolves the supplements or placebo in 30 cc of water and feeds the patient every 8 hours through a nasogastric tube. For this reason, the nurse, physician, and patient will not be informed of the type of supplement or placebo received during the study.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Artesh University of Medical Sciences
Street address
West Fatemi Ave, Tehran
City

Tehran

Province

Tehran

Postal code

9178939419

Approval date

2021-12-22, 1400/10/01

Ethics committee reference number

IR.AJAUMS.REC.1400.257

Health conditions studied

1

Description of health condition studied

Acute respiratory infection caused by coronavirus

ICD-10 code

J06.9

ICD-10 code description

Acute upper respiratory infection, unspecified

Primary outcomes

1

Description

28 days mortality

Timepoint

From the beginning of the intervention up to 28 days

Method of measurement

Record and view the file

2

Description

Serum level of acute phase reactive protein C

Timepoint

The beginning of the intervention and day 7

Method of measurement

Biochemically and using the appropriate kit

3

Description

Ratio of serum level of acute phase C-reactive protein to albumin

Timepoint

The beginning of the intervention and day 7

Method of measurement

Biochemically and using the appropriate kit

4

Description

ICU mortality

Timepoint

from beginning until ICU follow up

Method of measurement

Record and view the file

5

Description

The number of ventilator-dependent days

Timepoint

The beginning of the intervention until day 7

Method of measurement

Record and view the file

Secondary outcomes

1

Description

length of stay in the ICU

Timepoint

beginning of intervention until 7 days later

Method of measurement

record and view of files

2

Description

Serum levels of neutrophils and lymphocytes

Timepoint

beginning of intervention and 7 days later

Method of measurement

By biochemical methods and related kits

Intervention groups

1

Description

Intervention group: Oral supplement with high dose of carnitine capsule (1000 mg / 3 times a day) in patients with acute pulmonary infection due to coronavirus in the intensive care unit

Category

Treatment - Drugs

2

Description

Control group: Oral supplement supplement with starch capsule water (1000 mg / 3 times a day) in patients with acute pulmonary infection caused by coronavirus in intensive care unit

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Army 550-bed hospital

Full name of responsible person

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1

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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
Artesh 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

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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