

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the Effects of L-carnitine Supplementation on Clinical Outcomes in Hospitalized Patients with COVID-19

Protocol summary

Study aim

Determining the Effectiveness of L-carnitine Supplementation on Clinical Outcomes in Hospitalized COVID-19 Patients

Design

This clinical trial has two intervention and control groups, which are a total of 64 patients and are randomly divided into two groups. This study is a phase 3 clinical trial and is parallel and not-blinded.

Settings and conduct

This study is a clinical trial conducted in Shahid Beheshti Hospital in Hamadan at 2020. Patients who are admitted according to the inclusion criteria in this study are randomly divided to the intervention or control group. The control group will receive only routine medications and the intervention group will receive L-carnitine supplements in addition to these medications.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age 18 to 60 years: Positive PCR test: Hospitalization: Presence of Symptoms According to the Instructions of the Ministry of Health: Mild to moderate disease Exclusion Criteria: Pregnancy: Lactation: Severe Cardiovascular Disease: HIV Infection: History of Taking L-carnitine Supplement in the Past Month

Intervention groups

Patients in both intervention and control groups are routinely treated for COVID-19 according to the protocol of the Food and Drug Administration, but in addition to these routine drugs, the intervention group will receive 3 grams of L-carnitine supplement daily for 5 days.

Main outcome variables

Evaluation of clinical consequences of L-carnitine such as inflammatory factors like CRP, ESR and other factors such as ALT, AST, LDH, CPK, WBC, PT, INR and other

General information

Reason for update

Reduce the number of statistical samples according to

the circumstances: Eliminate numbers of primary outcome variables

Acronym

IRCT registration information

IRCT registration number: **IRCT20200921048794N1**
Registration date: **2020-11-19, 1399/08/29**
Registration timing: **prospective**

Last update: **2021-01-09, 1399/10/20**

Update count: **1**

Registration date

2020-11-19, 1399/08/29

Registrant information

Name

Mehran Ghasemi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 4627 4360

Email address

m.ghasemy@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-19, 1399/12/01

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 of the Effects of L-carnitine Supplementation

on Clinical Outcomes in Hospitalized Patients with COVID-19

Public title

Evaluation of the Effects of L-carnitine Supplementation on Patients with COVID-19

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 to 60 years
Positive PCR Test
Hospitalization
Existence of Corona Virus Symptoms According to the Instructions of the Ministry of Health
Mild to Moderate Disease Severity

Exclusion criteria:

Pregnancy
Breastfeeding
Severe Cardiovascular Disease
HIV Infection
History of Taking L-carnitine Supplementation in the Past Month
Requires Care in the ICU
Taking Anti-Inflammatory Drugs out of the Medication Regimen
Patients with High and Critical Disease Severity
Patient Dissatisfaction to Enter the Plan

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

We put 2 sheets A and two sheets B in an envelope and each time we remove one of the sheets, we place the patient in the control or intervention group. The removed sheet will not be returned to the envelope until the all of sheets in the envelope be finished. After randomly pulling out all four sheets, all sheets are returned to the envelope and the above procedure will be continued for the next four patients until the desired sample size is reached.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Hamadan University of Medical Sciences, Mahdih Street, in front of People's Park

City

Hamedan

Province

Hamadan

Postal code

6517838678

Approval date

2020-10-24, 1399/08/03

Ethics committee reference number

IR.UMSHA.REC.1399.650

Health conditions studied

1

Description of health condition studied

COVID-19

ICD-10 code

U07.1

ICD-10 code description

COVID-19, Virus identified

Primary outcomes

1

Description

C-Reactive Protein (CRP)

Timepoint

At the Beginning of Intervention (the Zero day) and the End of Intervention (Fifth day)

Method of measurement

Blood test

2

Description

Erythrocyte Sedimentation Rate (ESR)

Timepoint

Beginning and End of the Intervention

Method of measurement

Blood test

3

Description

O2 Saturation

Timepoint

Beginning and End of the Intervention

Method of measurement

Pulse Oximeter

4

Description

Complete Blood Count (CBC)

Timepoint

Beginning and End of the Intervention
Method of measurement
Blood test

5

Description
White Blood Cell (WBC)
Timepoint
Beginning and End of the Intervention
Method of measurement
Blood test

6

Description
Alanine Aminotransferase (ALT)
Timepoint
Beginning and End of the Intervention
Method of measurement
Blood test

7

Description
Lactate Dehydrogenase (LDH)
Timepoint
Beginning and End of the Intervention
Method of measurement
Blood test

8

Description
Creatine Phosphokinase (CPK)
Timepoint
Beginning and End of the Intervention
Method of measurement
Blood test

9

Description
Creatinine
Timepoint
Beginning and End of the Intervention
Method of measurement
Blood test

10

Description
Urea
Timepoint
Beginning and End of the Intervention
Method of measurement
Blood test

11

Description
Prothrombin Time (PT)
Timepoint
Beginning and End of the Intervention

Method of measurement
Blood test

12

Description
Red Cell Distribution Width (RDW)
Timepoint
Beginning and End of the Intervention
Method of measurement
Blood test

Secondary outcomes

1

Description
Fever
Timepoint
Beginning and End of the Intervention
Method of measurement
Patient File

2

Description
Cough
Timepoint
Beginning and End of the Intervention
Method of measurement
Questionnaire

3

Description
Mortality Rate
Timepoint
During the intervention
Method of measurement
Death of the Patient

4

Description
Duration of Hospitalization
Timepoint
Beginning and End of the Intervention
Method of measurement
Days

5

Description
ICU Referral
Timepoint
During the Intervention
Method of measurement
Observational

6

Description
Requires Ventilation

Timepoint

During the Intervention

Method of measurement

Observational

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

Control group: This hospitalized group receives only their routine medication regimen which includes Dexamethasone, Interferon beta and Favipiravir.

Category

Treatment - Drugs

2**Description**

Intervention group: The intervention group in addition to their usual treatment regimen received 1000 mg L-carnitine tablets of Karen Company for 5 days and 3 g daily, three oral tablets daily.

Category

Treatment - Drugs

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

Beheshti Hospital

Full name of responsible person

Dr Saman Talebi

Street address

Shahid Beheshti Hospital, Ghaem Square, at the beginning of Eram Blvd

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Hamadan

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Shahidbeheshti@umsha.ac.ir

Web page address

<http://beheshti.umsha.ac.ir/>

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

Hamedan University of Medical Sciences

Full name of responsible person

Saeed Bashirian

Street address

Vice Chancellor for Research and Technology,

Hamadan 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

Hamedan University of Medical Sciences

Proportion provided by this source

20

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**

Hamedan University of Medical Sciences

Full name of responsible person

Mehran Ghasemi

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Hamedan University of Medical Sciences

Full name of responsible person

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Associate Professor

Latest degree

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Mehran Ghasemi

Position

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Latest degree

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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