Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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, Mahdieh 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
City
Hamedan
Province
Hamadan
Postal code
3371-5-65179
Phone
+98 81 3838 0283
Email
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
City
Hamedan
Province
Hamadan
Postal code
6517838736
Phone
+98 81 3838 0717
Email
s_bashirian@yahoo.com
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
Street address
Faculty of Pharmacy, Hamadan University of Medical Sciences
City
Hamedan
Province
Hamadan
Postal code
6517838678
Phone
+98 81 3838 1593
Email
mehranghasemy76@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person
Rasool Haddadi

Position
Associate Professor

Latest degree
Ph.D.

Other areas of specialty/work
Pharmacology

Street address
Faculty of Pharmacy, Hamadan University of Medical Sciences

City
Hamedan

Province
Hamadan

Postal code
6517838678

Phone
+98 81 3838 1593

Email
haddadi.rasool@gmail.com

Person responsible for updating data

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

Street address
Faculty of Pharmacy, Hamadan University of Medical Sciences

City
Hamedan

Province
Hamadan

Postal code
6517838678

Phone
+98 81 3838 1593

Email
mehranghasemy76@gmail.com

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